UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

UNITED STATES OF AMERICA and THE STATE OF CALIFORNIA, *ex rel*. STEVEN HIGGINS Plaintiffs, v. BOSTON SCIENTIFIC CORPORATION Defendant.	)	Civil No. 11-sc-02453 (JNE/JSM) **Demand for Jury Trial**

RELATOR'S SECOND AMENDED COMPLAINT

TABLE OF CONTENTS

I. INTRODUCTION

1. The *qui tam* Relator, Steven Higgins, M.D., brings this action on behalf of the United States and the State of California to recover treble damages and civil penalties under the Federal False Claims Act and the California False Claims Act.

2. This action alleges a False Claims Act scheme knowingly perpetrated by Boston Scientific Corporation ("BSC" or "Boston Scientific") involving the FDA approval and subsequent sale of defective cardiac defibrillator devices known as Cognis and Teligen.

3. These cardiac defibrillator devices were supposed to deliver life-saving defibrillation ("shocks") or pacing therapy to a patient's heart when the patient was experiencing an arrhythmia, or abnormal heart rhythm. Instead, these devices suffered from serious, fatal defects in the design of their set screws, seal plugs, and header. These defects were inherent in all of the devices.

4. Unknowingly selling a defective device is not fraud. However, BSC knew that the devices were defective to the point of complete malfunction. As demonstrated in great detail below, while the FDA application was pending, and before Cognis and Teligen were even approved in May 2008, BSC learned that the devices suffered from serious set screw/header malfunctions based on its experience in Europe.

5. Starting in February 2008, physicians in Europe, initially in six different countries and 14 hospitals, began implanting the Cognis and Teligen devices in patients. Shortly thereafter, BSC received multiple reports of serious malfunctions with the set screw/header uncovered during and after the device implantation surgeries in Europe.

6. From this European experience, BSC knew prior to FDA approval in May 2008 – and also prior to the United States launch of Cognis and Teligen in August 2008 – that the devices were malfunctioning in a life-threatening manner. Further, soon after the United States launch,

BSC received an avalanche of reports, from U.S. implanters and BSC employees, regarding serious defects with Cognis and Teligen. Specifically, the devices were known to deliver inappropriate shocks to patients, and to fail to deliver shocks to patients when necessary to prevent possible cardiac arrest and death.

7. BSC should have immediately notified the FDA of these defects, or at least recalled the devices; instead, BSC undertook a concerted effort to minimize and downplay the Cognis and Teligen defects to allow the launch of the products in the United States and then to avoid an FDA recall after launch.

8. According to Relator's expert, if BSC had properly reported to the FDA the information BSC had regarding the defects in the devices, the FDA: 1) would have, at a minimum, delayed approval of the devices, and 2) would likely have denied the approval altogether. O'Reilly Declaration ¶ 13.

9. Despite knowing the devices were defective, BSC publicly attempted to blame physicians' implant techniques for the flaws, and even came out with revised implant instructions, in a "white paper" directed at "physician education."

10. Meanwhile, internally, BSC began work on a redesign of the header component and set screws that were causing the problems.

11. Then, in March 2009, BSC released a revised design that corrected the defects and began to sell "Version 2" of the Cognis and Teligen devices.

12. However, even after the corrected "Version 2" was available on the market, BSC continued to sell the original defective devices and patients continued to be implanted with the defective devices, up until July 2009 when the FDA announced a Class II recall.

13. From at least February 2008 when BSC launched Cognis and Teligen in Europe, and possibly earlier, until July 2009 when the devices were recalled in the United States, BSC made false and misleading statements and misleading omissions to the FDA regarding the devices including the following:

- BSC failed to submit Amendments to the FDA to their pending Pre-Market Approval (PMA) Supplements for Cognis and Teligen alerting the FDA as to the design defect problems encountered in Europe with the set screws/header;
- BSC failed to notify the FDA when it revised the Cognis and Teligen implant instructions for physicians as an attempt to remedy the defect;
- BSC instituted a policy of not submitting certain Adverse Event Reports regarding Cognis and Teligen to the FDA;
- The Adverse Event Reports that BSC did submit to the FDA were intentionally vague and omitted material information regarding the set screw design defect;
- During the fall of 2008 and the winter of 2009, BSC designed, manufactured and launched revised versions of Cognis and Teligen devices ("Version 2") which cured the design defect, yet BSC continued to sell the defective devices that remained on the market;
- BSC submitted misleading PMA Supplements regarding Version 2 of the devices, failing to disclose that the existing Version 1 devices had design defects that created serious risks of injury or death; and
- BSC misled the FDA about the severity of the defect leading up to the eventual Class II recall of the devices in July 2009.

Due to these false and misleading statements and omissions, the FDA was fraudulently induced to approve the devices in May 2008, and was fraudulently induced to allow the continued sale of the devices in the United States through 2008 and the first half of 2009.

14. As a result, government health care programs unwittingly paid for implantation of the defective devices in patients, *i.e.*, Boston Scientific knowingly caused hospitals and physicians to submit non-reimbursable claims to the government for defective Cognis and Teligen devices.

15. Plaintiff estimates that BSC caused approximately 30,000 false or fraudulent claims to be submitted to Medicare, Medicaid, and other federal health care programs for the implantation of defective Cognis and Teligen devices.

16. With an average reimbursement of over $35,000, these false or fraudulent claims for the defective Cognis and Teligen devices caused the government to suffer approximately $1 billion in damages.

II. JURISDICTION AND VENUE

17. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§1331, 1345.

18. This Court may exercise personal jurisdiction over BSC pursuant to 31 U.S.C. §3732(a) and because BSC transacts business in the District of Minnesota.

19. Venue is proper in the District of Minnesota under 31 U.S.C. §3732 and 28 U.S.C. §1391(b) and (c) because BSC resides in and/or transacts business in this District.

III. PARTIES

20. The United States is a plaintiff to this action on behalf of the Department of Health and Human Services ("HHS"), the Centers for Medicare and Medicaid Services ("CMS"), and other federally funded health care programs including Medicare, Medicaid, TRICARE, and the Veterans Administration.

21. Medicare is a government health insurance program for those 65 years or older, and those with certain disabilities. 42 U.S.C. §§ 426, 426A. Medicare is administered by CMS, which is part of HHS.

22. TRICARE/CHAMPVA ("TRICARE") is a federally funded program that provides medical benefits to military personnel, their families, retired veterans, and reservists called to duty. 32 C.F.R. § 199 *et seq.*

23. The Veterans Administration ("VA") is a federally funded and administered program which provides medical benefits to military veterans and their dependents.

24. The Medicaid Program, 42 U.S.C. § 1396 *et seq.*, is a government health insurance program funded jointly by the federal and state governments. Each State administers its own Medicaid program, but the State's programs are governed by federal statutes, regulations and guidelines. The federal portion of States' Medicaid payments, the Federal Medical Assistance Percentage, is based on a State's per capita income compared to the national average. During the relevant time period, the federal portion consisted of a minimum of 50% up to a maximum of roughly 80%.

25. Throughout the relevant time periods specified herein, the defective Cognis and Teligen devices were provided to recipients of benefits from Medicare, TRICARE, the Veterans Administration, Medicaid and other federally funded health care programs.

26. The State of California is a plaintiff in this action. Throughout the relevant time periods specified herein, defective Cognis and Teligen devices were provided to recipients of California's Medicaid Program, Medi-Cal, and paid for by Medi-Cal and the State of California.

27. Relator, Steven Higgins, M.D., is a citizen of the United States practicing medicine in La Jolla, California at Scripps Memorial Hospital ("Scripps"). At Scripps, he currently serves as the Director of Cardiac Electrophysiology, Chairman of the Department of Cardiology and Director of the Regional Cardiac Arrhythmia Center. He is Board Certified in cardiology, clinical cardiac electrophysiology and internal medicine. Dr. Higgins has been using implantable defibrillators in his practice since 1985, and is considered an expert in the field. Dr. Higgins has been a researcher for Boston Scientific and its predecessors since 1987, and an advisor and consultant for the company since 1994. Dr. Higgins has published over 120 scientific papers,

including three papers in the New England Journal of Medicine (NEJM) on the MADIT studies. The MADIT studies are considered the most important publications in the field of implantable defibrillators. From 1994 to 2009, Dr. Higgins was a senior member of the Cardiac Rhythm Management Medical Advisory Board (for Guidant – and later Boston Scientific after Boston Scientific purchased Guidant) and was intimately involved in the inner workings of the two corporations for 15 years. In 2009, Dr. Higgins worked half-time for Boston Scientific as "Consultant to the President" where he gained access to information about programs at Boston Scientific. In 2000, at a Guidant (later Boston Scientific) meeting, he was one of 30 honored by the Company as a "Pioneer in the History of the Implantable Defibrillator."

28. Defendant BSC describes itself as a worldwide developer, manufacturer, and marketer of medical devices. Boston Scientific is incorporated in the State of Delaware, with its principal executive office located in Natick, Massachusetts. In 2006, Boston Scientific acquired Guidant Corporation (now Guidant LLC), a medical device manufacturer. Boston Scientific's Cardiac Rhythm Management (CRM) division is located in St. Paul, Minnesota and is the division that researched, developed, manufactured and sold the cardiac devices at issue in this complaint, Cognis CRT-D and Teligen ICD.

IV. THE LAW

A. The Federal False Claims Act and the California False Claims Act

29. The Federal False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733, provides, *inter alia*, that any person who (1) "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," or (2) "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," is liable to the United States for a civil monetary penalty plus treble damages. 31 U.S.C. § 3729(a)(1)(A)-(B).

30. The terms "knowing" and "knowingly" are defined to mean "that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A)(i)-(iii). Proof of specific intent to defraud is not required. 31 U.S.C. § 3729(b)(1)(B).

31. The term "claim" means "any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that (1) is presented to an officer, employee, or agent of the United States; or (2) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government (a) provides or has provided any portion of the money or property requested or demanded; or (b) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded . . . ." 31 U.S.C. § 3729(b)(2)(A)(i)-(ii).

32. "[T]he term "material" means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4).

33. The California False Claims Act is modeled after the Federal FCA and contains comparable provisions to those detailed above. Relator asserts claims under the California False Claims Act for the State portion of the Medi-Cal false claims detailed in this Amended Complaint.

B. Government Regulation of Medical Devices

34. Congress enacted the Medical Device Amendments of 1976, 21 U.S.C. § 360c *et seq*. ("MDA"), to supplement the Food Drug and Cosmetic Act ("FDCA") and to "provide for the safety and effectiveness of medical devices intended for human uses." Pub. L. No. 94-295, 9 Stat. 539, 53 (May 28, 1976) (preamble). The MDA conferred greater authority on the Food and Drug

Administration ("FDA") to regulate medical devices and to prevent devices lacking evidence of safety and effectiveness from being marketed in the United States.

35. A medical device is defined by law as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals. . . ." 21 U.S.C. § 321(h).

36. Pursuant to its authority under the MDA, the FDA established three risk-based classifications for medical devices. Classes I, II, and III represent low, moderate, and high-risk categories respectively based on the intended use of the device. BSC's Cognis and Teligen are classified as Class III medical devices because they pose a high risk to patients and thus require special controls to provide reasonable assurance of safety and effectiveness. *See* 21 C.F.R. § 814.1 *et seq.*

1. <u>A Device Manufacturer Must Submit a Pre-Market Approval Application to the FDA Demonstrating Safety and Effectiveness to Receive Approval to Sell a Class III Medical Device</u>

37. Prior to selling or marketing a Class III device, the FDA requires companies like BSC to complete the "premarket approval process." To obtain pre-market approval, a manufacturer must submit a pre-market approval application ("PMA") to the FDA. 21 U.S.C. §360e(c)(1).

38. An original PMA must include, *inter alia*, a description of the device, indications for use, marketing history and technical data (non-clinical laboratory studies and clinical investigations) supporting safety and efficacy. 21 C.F.R. § 814.20(b). "The applicant or an authorized representative shall sign the PMA." *Id.* § 814.20(a).

39. The FDA can only approve a PMA if it determines that "there is a reasonable assurance of safety and effectiveness." 21 U.S.C. § 360e. The criteria involved in determining safety and effectiveness are:

> (1) The persons for whose use the device is represented or intended;
>
> (2) The conditions of use for the device . . . .;
>
> (3) The probably benefit to health from the use of the device weighed against any probable injury or illness from such use; and
>
> (4) The reliability of the device.

21 C.F.R. § 860.7(b).

40. After approval of a PMA, an applicant must "submit a PMA Supplement for review and approval by the FDA before making a change affecting the safety or effectiveness of the devices for which the applicant has an approved PMA." 21 C.F.R. § 814.39(a).

41. According to the regulations, a manufacturer must submit a PMA Supplement for all changes affecting the safety or effectiveness of the device, including any "[l]abeling changes," and changes "in the performance or design specifications, circuits, components, ingredients, principle of operation, or physical layout of the device." *Id.* at § 814.39(a)(2), (a)(6).

42. There are a few different types of PMA Supplements depending on the type of changes made to the device. A 180-day PMA Supplement is for significant changes that affect the safety and effectiveness of the device, allowing the FDA up to 180 days to conduct an in-depth review before approval.

43. The FDA regulations further state that "[a]ll procedures and actions that apply to an [original PMA] also apply to PMA supplements except that the information required in a supplement is limited to that needed to support the change." 21 C.F.R. § 814.39(c)(1); *see also*

O'Reilly Decl. ¶ 5. Thus, information from the original PMA is incorporated into the PMA supplement so as to avoid unnecessary resubmission of previously submitted information under the original PMA. *Id.* ¶ 6.

2. A Device Manufacturer Must Amend its PMA Supplement with New Safety and Effectiveness Information

44. After submitting a PMA Supplement but prior to approval, FDA regulations specifically mandate that the applicant file an amendment to its PMA or PMA Supplement with any new safety and effectiveness information: "[t]he applicant shall periodically update its pending application with new safety and effectiveness information learned about the device from ongoing or completed studies that may reasonably affect an evaluation of the safety or effectiveness of the device or that may reasonably affect the statement of contraindications, warnings, precautions, and adverse reactions in the draft labeling." 21 C.F.R. 814.20(e); O'Reilly Decl. ¶ 9; *see also* 21 C.F.R. § 814.37.

45. Federal law prohibits a medical device manufacturer from submitting any report, such as a PMA Supplement or Amendment, which is false or misleading in any material respect. 21 U.S.C. §331(q)(2), (y)(1).

3. A Device Manufacturer Must Submit Detailed Adverse Event Reports to the FDA

46. In addition to the obligation noted in the previous subsection relating to pending PMA supplements and the duty to advise the FDA of safety issues, a device manufacturer must establish and maintain procedures for receiving, reviewing and evaluating complaints about its medical devices. 21 C.F.R. § 820.198(a). In this regard, manufacturers must evaluate whether the complaint represents an adverse event required to be reported to the FDA, as discussed below. *Id.* Any complaint involving the possible failure of a device to meet any of its specifications must be

reviewed, evaluated and investigated, and a detailed record of the investigation must be maintained. *Id.* § 820.198(c)-(e).

47. If the manufacturer becomes aware of information, from any source, that reasonably suggests that its device: a) may have caused or contributed to a serious injury or death, or b) malfunctioned and the device would be likely to cause or contribute to a death or serious injury if the malfunction recurred, the manufacturer must submit an Adverse Event Reports to the FDA. 21 C.F.R. § 803.3.

48. A medical device causes or contributes to a serious injury or death when the outcome was or may have been attributed to the device, or the device was or may have been a factor in a death or serious injury, including events which occur as a result of failure, malfunction, improper or inadequate design, manufacture, labeling, or user error. 21 C.F.R. § 803.3. Malfunction means the failure of the device to meet its performance specifications or otherwise perform as intended. 21 C.F.R. § 803.3.

49. The Adverse Event Reports are generated using FDA Form 3500A and must include very specific information, including, *inter alia*, details about the patient (Block A of the Form), the adverse event (Block B), and the device involved (Block D). 21 C.F.R. § 803.52(a)-(c).

50. The particular adverse event information includes identification of the adverse event, outcomes attributable to the event, date of the event, a "[d]escription of the event or problem, including a discussion of how the device was involved, nature of the problem, patient follow-up or required treatment, and any environmental conditions that may have influenced the event[.]" *Id.* § 803.52(b). The report must include the date of the implant and device explanation (if

applicable), "[w]hether the device was available for evaluation, and whether the device was returned to [the manufacturer], and if so, the date it was returned to you." *Id.* § 803.52(c).

51. Further, the regulations list specific reporting requirements for device manufacturers (Block H) that must be included in the Adverse Event Report:

> (1) Type of reportable event (death, serious injury, malfunction, etc.);
> (2) Type of followup report, if applicable (e.g., correction, response to FDA request, etc);
> (3) *If the device was returned to you and evaluated by you, you must include a summary of the evaluation. If you did not perform an evaluation, you must explain why you did not perform an evaluation*;
> (4) Device manufacture date (month, day, year);
> (5) Whether the device was labeled for single use;
> (6) Evaluation codes (including event codes, method of evaluation, result, and conclusion codes) (refer to FDA MedWatch Medical Device Reporting Code Instructions);
> (7) Whether remedial action was taken and the type of action;
> (8) Whether the use of the device was initial, reuse, or unknown;
> (9) Whether remedial action was reported as a removal or correction under section 519(f) of the Federal Food, Drug, and Cosmetic Act, and if it was, provide the correction/removal report number; and
> (10) Your additional narrative; and/or
> (11) Corrected data, including:
> (i) Any information missing on the user facility report or importer report, including any event codes that were not reported, or information corrected on these forms after your verification;
> (ii) For each event code provided by the user facility under § 803.32(e)(10) or the importer under § 803.42(e)(10), you must include a statement of whether the type of the event represented by the code is addressed in the device labeling; and (iii) If your report omits any required information, you must explain why this information was not provided and the steps taken to obtain this information.

21 C.F.R. § 803.52(f) (emphasis added).

52. The FDA posts Adverse Event Reports to its Manufacturer and User Facility Device Experience ("MAUDE") database, which is available to physicians and the public so that they can be aware of the risks of the device. 21 C.F.R. § 803.9.

53. However, the FDA team involved in posting MAUDE reports is separate from the specific FDA product review teams charged with substantively evaluating Supplemental PMA's.

54. Therefore, in addition to filing Adverse Event Reports for publication in MAUDE, a Supplemental PMA applicant such as BSC is legally required to identify and explain all available risk and effectiveness data to the Center for Devices and Radiological Health ("CDRH") device review team assigned to the PMA Supplement(s) in question. O'Reilly Decl. ¶ 9. Specifically, 21 C.F.R. § 814.20(e) mandates submission of the information described below (to the CDRH device review team):

> (e) The applicant shall periodically update its pending application with new safety and effectiveness information learned about the device from ongoing or completed studies that may reasonably affect an evaluation of the safety or effectiveness of the device or that may reasonably affect the statement of contraindications, warnings, precautions, and adverse reactions in the draft labeling. The update report shall be consistent with the data reporting provisions of the protocol. The applicant shall submit three copies of any update report and shall include in the report the number assigned by FDA to the PMA. These updates are considered to be amendments to the PMA……

4. A Device Manufacturer's Duty to Report Medical Device Corrections to the FDA

55. If a medical device manufacturer makes a "correction" to a medical device, it must submit a written report to the FDA within 10 days if the correction was initiated to reduce a risk to health posed by the device. 21 U.S.C. §360i(g); 21 C.F.R. §806.10.

56. "Correction means the repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a device without its physical removal from its point of use to some other location." 21 C.F.R. §806.2(d).

57. "Risk to health means (1) a reasonable probability that use of, or exposure to, the product will cause serious adverse health consequences or death; or (2) that use of, or exposure to, the product may cause temporary or medically reversible adverse health consequences, or an outcome where the probability of serious health consequences is remote." 21 C.F.R. §806.2(j).

58. The correction or removal of a device that the FDA considers to be in violation of the FDCA and against which the FDA would initiate legal action is called a "recall." 21 C.F.R. § 7.3(g).

5. A Device Manufacturer's Duty to Recall a Defective Medical Device

59. A recall involves the removal from the market of a product which presents a risk of injury or is otherwise defective. 21 C.F.R. § 7.40 *et seq*. Recalls may be conducted on a manufacturer's own initiative, by FDA request or by FDA order. *Id.*; 21 C.F.R. § 810.10 *et seq*. A manufacturer may recall a device if it presents a risk of injury or gross deception or is otherwise defective. 21 C.F.R. § 7.40. If a manufacturer fails to initiate a recall, the FDA will request the manufacturer to conduct one, if the device presents a risk of injury or gross deception or is otherwise defective. *Id.* § 7.45.

60. Based on a number of factors, the FDA evaluates the health hazard presented by the device being recalled or considered for recall and assigns the recall a classification of Class I, Class II or Class III, to indicate the relative degree of health hazard presented:

- **Class I recall:** a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.

- **Class II recall:** a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

- **Class III recall:** a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.

21 C.F.R. § 7.41.

V. BOSTON SCIENTIFIC'S DEFECTIVE IMPLANTABLE CARDIAC DEFIBRILLATOR DEVICES, COGNIS AND TELIGEN

61. Both Cognis and Teligen are implantable defibrillators, which are designed to prevent sudden cardiac death by detecting and treating cardiac arrhythmia, a dangerous condition in which an individual's heart beats too fast (ventricular tachycardia) or too fast and irregular (ventricular fibrillation).

62. When a defibrillator detects an arrhythmia, it delivers a potentially life-saving "shock" or pacing therapy to the heart to restore it to a normal rhythm. Left untreated, heart arrhythmias may lead to cardiac arrest, death, or other serious injuries.

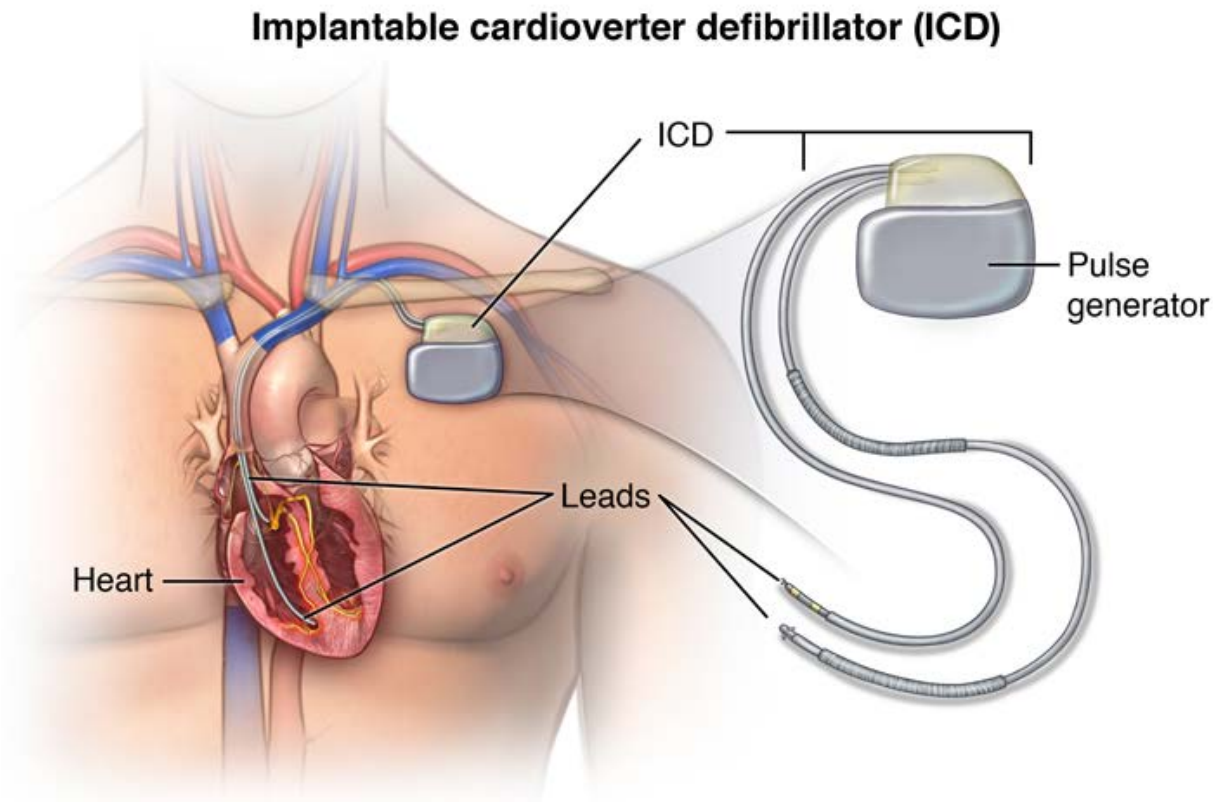
63. More specifically, defibrillators are surgically implanted in the patient's chest wall and are connected to the patient's heart by electrical wires called "leads." The devices at issue here contain a titanium pulse generator, a battery, a small computer, and the electrical leads. The leads are connected to the pulse generator through the "header," a medical plastic cap on the top of the pulse generator. The leads are inserted into the openings or "ports" in the header. The leads are then secured by "set screws" which are screwed down - using a calibrated torque wrench - to trap the lead between the set screw and pulse generator, thus forming a reliable electrical connection.

64. The set screws are covered by "seal plugs" which are pre-slit to permit insertion of the torque wrench which is used to tighten down the set screws. In order for the battery-powered pulse generator to track a person's heart rate and deliver an electrical shock when necessary, the

leads must be properly attached to the device. If the leads are not properly attached, the device will malfunction.

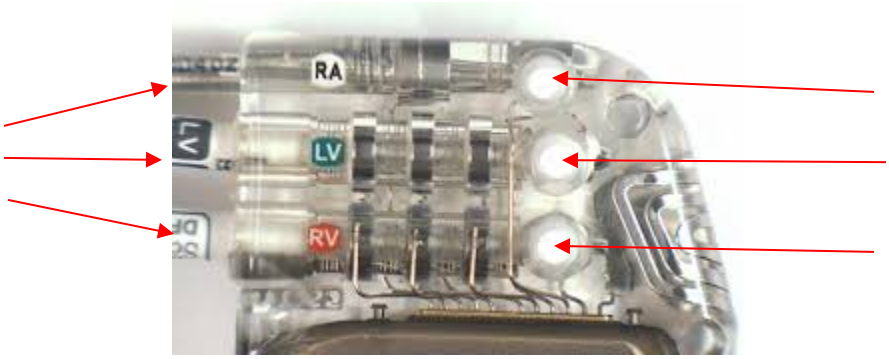
65. While both Teligen and Cognis are implantable defibrillators, the Teligen ICD device has either one or two leads inserted in the right side of the heart, whereas the Cognis CRT-D device utilizes an extra lead in the left ventricle which helps the heart to pump more efficiently and is indicated to treat heart failure. Thus, while both devices are designed to deliver a life-saving electrical shock when necessary, the Cognis CRT-D device has the additional lead which makes the heart pump in a coordinated way, improving symptoms of heart failure.

66. A generic image of a cardiac defibrillator and how it functions within the body appears below:



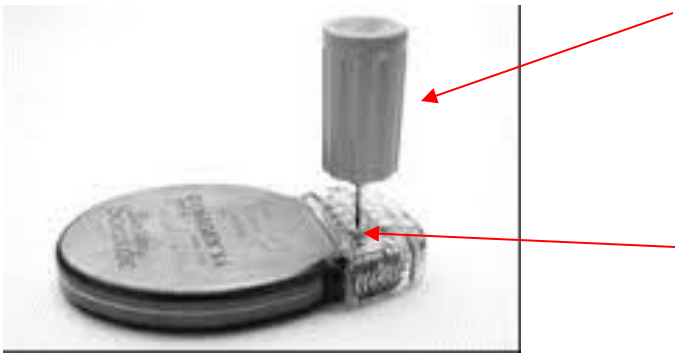
67. Images of Boston Scientific's Cognis and Teligen implantable cardiac defibrillators, before lead insertion, appear below:

68. A generic close up image of an ICD header, with three leads inserted, appears below:

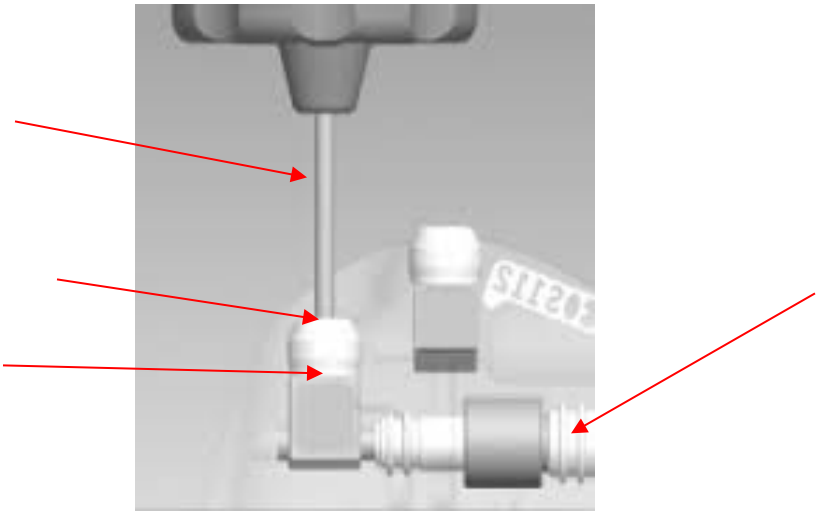


69. Beneath the seal plug are set screws. An electrophysiologist implanting an ICD uses a torque wrench – a calibrated screwdriver – to tighten the set screws. The torque wrench is inserted into the seal plug to grasp the top of the set screw so that it can be tightened. Once the screw is tight, the torque wrench "clicks," much like the gas cap on a car clicks when the cap is screwed closed.

70. A generic image of a torque wrench inserted into a seal plug appears below.



71. Below is a generic close up image of a torque wrench, inserted into a seal plug, with a lead inserted into the port:



72. The defects in the Cognis and Teligen devices that are the subject of this Amended Complaint caused several life-threatening problems with the devices.

73. For example, as the screws were tightened by surgeons, air could not escape. This caused air pressure to build at the site within the port where the screw was supposed to secure the electrical lead. As the physician continued to advance the screw, the pressure built to the point where:

a) the torque wrench "clicked," leading the physician to believe the lead was secure, when in fact there was either no electrical connection or a loose/intermittent connection,

b) the lead was pushed outward from the connection site, causing either no electrical connection or a loose/intermittent connection, or

c) the lead was "burped" out from the connection site altogether, causing there to be no electrical connection of any kind.

74. In other instances, as the screws were tightened, they "fouled" the threads, leading the torque wrench to "click" and the surgeon to believe the lead was secure, when in fact the set screw had not secured the electrical lead at all.

75. Where no electrical connection existed, the device was effectively useless: even if the leads attached to the patient's heart detected a problem which required the device to shock the patient, no such shock could be delivered because no electrical connection existed between the battery/pulse generator and the leads attached to the patient's heart.

76. Where the electrical connection was intermittent, this "on-and-off" connection caused electrical "noise" which the devices detected as an abnormal heart rhythm, which triggered the device to deliver a painful (and dangerous) electric shock to the patient's heart, when in fact the heart was beating normally.

VI. BSC KNOWINGLY MISLED THE FDA ABOUT COGNIS AND TELIGEN PRIOR TO FDA APPROVAL AND THE UNITED STATES LAUNCH OF THE DEVICES

77. Prior to the FDA approval to sell Cognis and Teligen in the United States, BSC launched the devices in Europe. Through the European launch, BSC learned about the problems with the set screw/header configuration from complaints from European physicians and customers about the devices. BSC failed to amend its FDA submission to reflect these problems in Europe and the FDA unknowingly approved the devices which permitted BSC's subsequent sale of the devices in the United States.

A. The Successful Launch of Cognis and Teligen in the United States was Extremely Important to BSC

78. The successful launch of Cognis and Teligen in the United States was extremely important to BSC's image as well as its bottom line.

79. In 2006, BSC acquired Guidant, a medical device manufacturer specializing in, among other things, cardiac rhythm management devices (pacemakers and defibrillators).

80. For years leading up to the acquisition, Guidant had been plagued with FDA recalls for faulty medical devices. Further, Guidant had been accused on several occasions of having covered up defects, delayed corrective actions and sold known defective devices into the market.

81. After the acquisition, BSC continued to manufacture many of the Guidant-labeled cardiac devices which continued to experience problems.

82. To revamp its image in the Cardiac Rhythm Management (CRM) field and distinguish itself from Guidant (and the problems customers associated with Guidant), BSC launched its "CRM Identity Campaign" in or around 2007, aimed at convincing customers (doctors and hospitals) that BSC's CRM Division was "(Re)Engineered, (Re)Focused, [and] (Re)Vitalized." Boston Scientific PowerPoint, *CRM Sales Q2 2008 POA Meeting*.

83. The "(Re)Engineered" prong of its message refers to "Project Aurora," BSC's highly-touted program to improve engineering related to its devices in order to improve safety and quality. Over 600 employees were dedicated to "Project Aurora," a program designed to positively impact "every aspect of the product from design through production." Further, the "(Re)Focused and (Re)Vitalized" part of BSC's message were intended to support BSC's introduction of new and improved CRM products to its customers.

84. BSC instructed all sales representatives to "[C]ommunicate & reinforce the (Re)Engineered, (Re)Focused, (Re)Vitalized messages with every customer." Boston Scientific

PowerPoint, *CRM Sales Q2 2008 POA Meeting*. Sales representatives were encouraged to use a whole host of CRM Identity Messaging support materials provided by BSC.

85. The physician/customer's perception of BSC/CRM was key – BSC tracked how well the "CRM Identity Campaign" was doing based on surveys of physicians' favorable, neutral or unfavorable impressions of BSC. By the second quarter of 2008, BSC in an internal document proclaimed that it had reached its goal with a 53% "Favorable" customer perception rating for BSC's CRM among electrophysiologists (the physicians who generally implant defibrillators).

86. Importantly, the launch of Cognis and Teligen in 2008 was the centerpiece of BSC's CRM Identity Campaign. Cognis and Teligen were designed to be among the first BSC-branded cardiac devices to go on the market (prior to 2008, all of BSC's cardiac devices were still labeled with the "Guidant" name).

87. Further, these devices were extremely important to the continued success of the company in terms of revenue-generation, generating billions of dollars in sales. In fact, in 2008 and 2009, approximately twenty-five percent of BSC's $8 billion in sales were attributable to sales of Cognis and Teligen.

B. BSC Sought FDA Approval of the Implantable Cardiac Devices Cognis and Teligen in December 2007

88. On December 7, 2007, BSC submitted PMA Supplements (P010012/S165 for Cognis and P960040/S155 for Teligen) for two lines of implantable cardiac devices, Cognis CRT-D (Cardiac Resynchronization Therapy Defibrillator; model numbers N118 and N119) and Teligen ICD (Implantable Cardioverter Defibrillator; model numbers E102 and E110).

89. The original pre-market approval application ("PMA") on which the Cognis' approval is based is from 2002 and for the Contak device. And, Teligen's approval is based on the original PMA for Ventak filed in 1996. The Original PMAs (P010012 and P960040) provide

summaries of and data supporting the safety and effectiveness of the implantable cardiac defibrillators.

90. BSC heralded Cognis and Teligen as "Revolutionary" new cardiac devices. President and CEO Jim Tobin proclaimed, "Cognis and Teligen are truly breakthrough technologies featuring significant engineering advances. . . . These products are testaments to the revitalization of our CRM business . . . ." Cognis and Teligen were smaller and thinner than competitive devices manufactured by competitors Medtronic and St. Jude Medical. They were touted as having a host of additional improvements over predecessor cardiac devices, including an "[i]mproved header, set screws and seal plugs." Boston Scientific PowerPoint, *COGNIS-TELIGEN: Sharp Technical Overview*, June 2008.

91. Specifically, BSC redesigned the set screw configuration and design by making a number of changes such as eliminating the "retainer washer" so that the "[s]et screw cannot escape" and by reducing the total number of set screws by adding "spring connector[s]" to replace set screws. *Id.* BSC reengineered the seal plugs by changing their color to white and making them "[m]ore lubricious." *Id.* Further, BSC unveiled a new, redesigned torque wrench for inserting and removing the set screws.

92. BSC explained that the Cognis and Teligen devices represented "entirely new platforms" and were "the result of a multi-year research and development effort" to completely redesign the devices. Boston Scientific Press Release, *Boston Scientific Announces FDA Approval for New Devices to Treat Heart Failure and Sudden Cardiac Death*, May 19, 2008.

C. Prior to FDA Approval of Cognis and Teligen, BSC Learned About Serious Malfunctions Involving the Set Screw/Header Based on the European Launch of the Devices

93. As stated above, BSC submitted an application to the FDA for approval of Cognis and Teligen in December 2007. While that application was still under review, BSC began a market

launch of the devices in Europe in February of 2008. In late February 2008, physicians in Europe began implanting the Cognis and Teligen devices in patients. Initially, physicians in six different countries and 14 hospitals performed 40 implants of the devices. This was the beginning of the market launch in Europe and was expanded throughout the winter and spring of 2008.

94. During that time, BSC began receiving reports of problems with the devices from Europe, including problems with the set screw/header configuration.

95. As discussed at length herein, the Cognis and Teligen defects have to do with the design of the set screws, header and seal plugs. As discussed above, the re-design caused at least two separate problems.

96. First, as the physician screwed down the set screw with the torque wrench, the air within the header could not escape. This led to air pressure buildup around the lead, which could force the lead out of the port ("burping"), immediately or at a later time, even when the torque wrench "clicked" and thereby indicated that the screw was fully tightened to the lead.

97. Second, if the physician did not position the torque wrench at precisely 90 degrees, the set screw could "foul" the threads while it was being screwed down, *i.e.*, the torque wrench "clicked" even though the screw was not connected, or fully connected, to the lead.

98. Due to the air pressure build-up and/or fouled threads, the defective design of the set screws/header prevented the leads from being securely connected to the pulse generator in some instances.

99. These connection defects in the set screw/header design of Cognis and Teligen caused lead-to-device connection problems with serious and potentially fatal consequences for patients. The potential problems caused by the set screw/header defects fall into two major categories, "oversensing" and "undersensing."

100. Oversensing involves the device "seeing" or sensing electrical noise that is not actually a heart rhythm abnormality, but which is misinterpreted by the device and results in the administration of an unnecessary shock. In addition to the anxiety or discomfort caused to the patient, this unnecessary administration can use up the device's limited battery capacity to deliver shocks. More importantly, an unnecessary and untimed shock itself can cause a life-threatening arrhythmia such as sudden death.

101. The second category, undersensing, means that the device fails to detect a life-threatening heart rhythm or is unable to actually deliver the necessary shock due to the lead connection problem. In this worst case situation, an implanted defibrillator cannot deliver life-saving therapy, which can cause sudden death or other serious bodily harm.

102. In either scenario, the device obviously does not operate as intended and cannot perform its core life-saving function.

103. In response to the complaints emanating from Europe about the devices, BSC dispatched Sumi Dahm, head of the engineering team responsible for Cognis and Teligen, and members of his team, to investigate and deal with the complaints, including problems with the set screw/header configuration. In connection with this experience in Europe, BSC's engineering team developed coaching and implant technique changes to the process of attaching the leads to the set screw/header design featured on the just-released Cognis and Teligen devices. These implant technique changes were not a real fix for the design problem, but rather were ineffective "workarounds" or stop-gap measures.

D. BSC Misled the FDA About Cognis and Teligen Prior to Their FDA Approval and Launch in the United States

104. As noted, BSC was obligated to amend its pending PMA Supplements for Cognis and Teligen with new information learned regarding safety and effectiveness. 21 C.F.R. § 814.20(e); *see also* 21 C.F.R. § 814.37.

105. BSC failed to amend its pending PMA Supplements to alert the FDA as to the set screw/header malfunctions that it learned about through complaints received from Europe.

106. By failing to submit an amendment regarding the problems encountered by physicians and patients in Europe, BSC misled the FDA in its review of the devices.

107. Further, the malfunctions experienced in Europe rendered the PMA Supplements (and Original PMAs on which the Supplements relied) submitted by BSC false and misleading by omission. Stated differently, these FDA filings claimed that the devices were safe and effective for the treatment of patients with certain cardiac conditions, when in fact the devices were defective, and BSC knew it.

108. Without the additional information about Cognis and Teligen which BSC learned from the European launch, the FDA approved the devices on May 8, 2008 for sale in the United States. *See* Exhibits 1 and 2.

109. The failure to file amendments to the pending PMA Supplements for Cognis and Teligen would have been material to the FDA approval.

110. Relator's expert states that, by failing to alert the FDA about the problems encountered in Europe, "BSC misled the FDA's product review team." O'Reilly Decl. ¶ 11. Further, Relator's expert states that:

> FDA product review team decisions are focused on disclosure and analysis of risks. . . . It is the obligation of the sponsor to deliver risk data to the applicable FDA review team, and BSC should have delivered the risk information outlined in the complaint to the FDA

> product review team that BSC knew was considering its Supp-PMAs for Cognis and Teligen.
>
> It is not sufficient to merely make a routine filing of the FD3500A forms for entry into the MAUDE data bases as part of that system's aggregation of all device experiences.

Id. ¶ ¶ 11-12.

111. Relator's expert ultimately concluded: "[i]f the information in the complaint is true, reporting the risk information outlined in the complaint to the CDRH's product review team *would have delayed approval of the Supp-PMAs at issue, and is likely to have led to their denial*. *Id.* ¶ 13 (emphasis added).

112. Although the devices were not launched in the United States until almost three months later, BSC still did not fully disclose the extent of the problems to the FDA prior to selling the devices in the U.S.

113. Further, BSC concealed the set screw/header issues from its employees and others leading up to the launch of the devices in the United States in August of 2008. In May and June of 2008, BSC sponsored a series of Cognis/Teligen "Tech Nights" for all field sales representatives. At these events, the Company provided technical training, but failed to mention any issues with the set screws/header design. Instead, BSC assured them that their "COGNIS-TELIGEN training will prepare Reps for real-life scenarios from day one." Boston Scientific PowerPoint, *CRM Sales Q2 2008 POA Meeting*.

114. Similarly, in July 2008 (just one month prior to the August 2008 launch) BSC's Medical Advisory Board (MAB), an independent group of 8-10 electrophysiologists, including the Relator, met for a series of meetings over three days.

115. The central purpose of the MAB is to provide guidance and advice to the Company regarding safety issues related to its products.

116. Relator served on the MAB from approximately 1999 to 2009.

117. Relator attended the July MAB meetings at which BSC asked for guidance regarding various topics including finance (where to cut back on spending, financial implications of recalls, etc.) and strategy (potential new directions - heart failure sensor, competitive intelligence, etc.).

118. BSC did not mention any of the problems or issues with Cognis or Teligen that were being experienced in Europe, despite the fact that such issues were squarely within the mandate of the MAB.

119. On August 1-3, 2008, BSC held its National Launch Training for Cognis and Teligen. BSC flew over 1000 employees to New Orleans for the training, which was held at the Marriott just off Bourbon Street in downtown New Orleans. The purpose of the meeting was to train its sales force on the new devices, including how to assist doctors in implanting the devices.

120. Notwithstanding the presence of its national sales force, BSC did not once mention the set screw/header problem at the National Launch Training.

VII. BSC CONTINUED TO KNOWINGLY MISLEAD THE FDA DURING THE UNITED STATES LAUNCH OF COGNIS AND TELIGEN

A. BSC Misleadingly Blamed Physicians' Implant Technique for the Defects

121. As noted above, the CRM Identity Campaign and Project Aurora were widely promoted by BSC as heralding a new era in safety and effectiveness for BSC products. Prior to launch, the company touted Cognis and Teligen as being among the first devices to be released under the BSC brand. The company aggressively – and misleadingly – led physicians down a road of misinformation regarding these new devices and how safe they were for patients.

122. The campaign was successful (at least for a short time). As noted above, BSC launched Cognis and Teligen in the United States on August 4, 2008. Cardiologists and

electrophysiologists across the United States immediately began utilizing the devices and implanting them in patients.

123. However, within days of launch, BSC was receiving reports from all over the country regarding the devices malfunctioning, specifically, problems with the set screws/header of the devices such that the leads were burping out, or were able to be pulled out despite the torque wrench's indication that the set screw was fully tightened and the connection was secure.

124. Less than three weeks after launch, and in an effort to avoid a recall of Cognis and Teligen in the wake of a huge volume of reported defects, BSC misleadingly introduced revised implant instructions which suggested that the problems had to do with the implant techniques used by physicians. These revised instructions were merely an attempt to workaround the problems with the defective devices and, ultimately, did not fix the defects.

125. These revised instructions were published on August 21, 2008 in a white paper titled "A Closer Look." In order "to ensure a successful lead connection for ICDs and CRT-Ds with white seal plugs[,]" BSC instructed implanting physicians to release any trapped air or fluid from the header by inserting the wrench into the seal plug, holding the wrench precisely at a 90 degree angle, inserting the lead, screwing down the set screw, and then performing a physical "tug test" (pulling on the lead to see if it was secure). Boston Scientific, *A Closer Look*. Around the same time, BSC also released an instructional video on its website demonstrating how to connect the leads to the devices, the first time BSC had ever used video instruction on its website.

126. These revised implant instructions were an attempt to "workaround" the serious defects with Cognis and Teligen, rather than addressing the defects through the regulatory process.

127. Specifically, the new implant instructions were akin to a change to the labeling of the devices and should have been submitted as a PMA Supplement for FDA approval. *See* 21

C.F.R. §814.39(a)(2) (a manufacturer must submit a PMA supplement for all changes affecting the safety or effectiveness of the device, including any labeling changes). Further, a properly filed FDA submission would have drawn attention to the set screw/header problem. Thus, BSC continued by omission to mislead the FDA about the severity of the set screw/header defect by failing to submit a PMA Supplement.

128. In or around Labor Day 2008 (approximately one month after launch), BSC re-trained its entire sales force as to "revised" implant techniques. This re-training was done over conference calls, and then each regional manager was required to host a "training night" for that region's sales representatives. The sales force was instructed as to the revised implant techniques (release air/fluid from the header, 90 degree angle with wrench, tug test, etc.). The sales force was also instructed to *stand close to the doctor and watch his/her hands*, so as to make sure the doctor put the lead in the header and let the air escape (and to make sure the sales person was close enough to ask the doctor to do a "tug test.").

129. Thus, BSC taught its sales people a workaround which it expected doctors to use during operations on humans, but BSC did not advise its sales people or doctors *why* these workarounds were developed, *i.e.*, BSC did not (at least yet) admit to the design defect.

130. These revised instructions were highly unusual because typically connecting the leads to a cardiac defibrillator is a straightforward, uncomplicated part of implant surgery.[1]

[1] Previously, in approximately March 2008, BSC undertook an effort to minimize or conceal the defects by post-hoc revisions to the U.S. physician instruction manuals for older cardiac devices, apparently to give the impression that the problems with the set screws/header pre-dated or were not unique to Cognis and Teligen. Specifically, BSC revised its ICD System Guide for Prizm II and Vitality, devices which were originally released in 2003. BSC revised the instructions having to do with how to insert the leads and set screws into these devices, adding, for example, the instruction to do a "tug test" or pull on the lead to make sure it was secure. This insertion of new instructions was peculiar because these older cardiac devices were no longer available in the United States and thus, were no longer being implanted here.

131. In a fourth quarter 2008 Plan of Action (POA) PowerPoint distributed to all Regional Sales Managers, BSC suggested that sales representatives respond to physicians who complain of lead connection problems by stating:

> - The COGNIS and TELIGEN header was redesigned based on physician input. With these design enhancements to improve reliability and usability come some important but slight changes in implant technique.
>
> - We have a number of resources available to help you better understand these changes including a Closer Look article and a demonstration video.

132. By telling its sales representatives to state that the header was redesigned based on physician input, BSC implied that there was some sort of demand by doctors for a re-designed device, when in fact, there was no demand for a re-engineered set screw and header, at least not in the medical literature. The redesign was viewed by many as "a solution to a non-problem." What BSC failed to disclose was that the revised instructions were attempting to – but did not – fix the set screw/header design defects with Cognis and Teligen. Even after re-training doctors and salespeople, the devices continued to malfunction at an alarming rate.

B. BSC Received Complaints from Across the Country Regarding the Cognis and Teligen Defects

133. Almost immediately after launch, BSC received an avalanche of reports relating to the defects described herein.

134. By way of example, doctors at The Texas Heart Institute (THI) at St. Luke's Episcopal Hospital, one of the premier cardiac centers in the country, began using the devices upon launch. They immediately began having trouble with the set screw/header defects.

135. Within two weeks of launch, some THI physicians, instead of simply complaining to BSC sales representatives, took their concerns straight to BSC management.

136. The concerns communicated by the THI physicians alarmed BSC's management.

137. In response to the complaints from THI, Sumi Dahm, head of BSC's engineering team responsible for Teligen and Cognis, members of his engineering team, and several high-ranking BSC executives (*e.g.*, John Knighten, Area Vice President of Sales) flew to Houston to meet with the doctors and to allay their concerns.

138. During the meeting, Sumi Dahm admitted to the THI physicians that BSC was aware of the malfunctions involving the set screws/headers *because the devices had been launched earlier in the year in Europe and similar problems had occurred there and had been reported to BSC.*

139. Dahm subsequently provided the Houston doctors with new instructions regarding implant techniques for the devices, including the "tug test" where the physician pulls on the lead to see if the set screw has secured the lead properly.

140. BSC was able to share these implant technique changes so quickly after launch because it had been dealing with the same problems in Europe prior to the United States launch, and had taken advantage of that experience to develop various "workarounds." Again, however, these efforts did not fix the defects inherent to the devices.

141. After the Houston meeting, Dahm and his team travelled to Spokane, Washington to address a customer's complaints about the functioning of the Cognis and Teligen devices. Again, the BSC team indicated that they had seen these problems with the devices before and demonstrated the revised implant technique. BSC's Area Vice President of Sales, Ryan Walters, attended the meeting.

142. Upon information and belief, the set screw/header defect was so common and widespread that Dahm and his engineering team from BSC traveled all across the country meeting with customers who were having problems with the defective Cognis and Teligen devices.

143. It was alarmingly common for the defects in Cognis and Teligen to cause problems during surgery. In many instances, physicians would screw the set screws all the way down, yet still be able to "tug" the leads out of the device; so, the physician would have to retract the set screws, re-insert the leads and screw down the set screws again. By Relator's estimate he encountered such problems in 25% of Cognis and Teligen surgeries.

144. If a physician failed to perform the tug test – which many physicians did, because prior versions of the devices, and other ICD's on the market, did not require this workaround – the question of whether there was a secure electrical connection between the patient's heart and the devices was at best unknown, and at worst non-existent.

145. In addition to causing complications during surgery, the set screw/header defect often caused the patient to require a re-operation. In this situation, before a life-threatening arrhythmia, a non-invasive test of an implanted device might reveal evidence of an improper set screw-device interface, manifesting as an abnormal lead impedance. If uncovered, the patient would then be subjected to an additional surgery which entailed the risk of anesthesia, infection, pain and discomfort.

146. Further, the patient's insurance, including government health care programs, would likely be billed for the cost of a second operation.

147. After surgery, the exact frequency of the defects affecting patients is even harder to quantify. The frequency of the defects affecting patients post-surgery is hard to estimate because lead(s) that "burped" out after surgery could have led the device to fail to deliver a necessary shock and the patient could have died of sudden death or suffered other serious cardiac or neurologic events. In that scenario, it may not have been apparent that the defects caused the device to

malfunction. The patient's family or physician may have mistakenly assumed that this sudden death was unavoidable, attributed to known heart disease.

C. BSC Instituted an Unlawful Policy Regarding Adverse Event Reports to the FDA

148. As discussed above, federal law requires device manufacturers to submit an Adverse Event Report to the FDA any time the manufacturer becomes aware that device "malfunctions" and if the malfunction recurred it would be likely to cause death or a serious injury. 21 C.F.R. § 803.3. A device malfunctions when it fails to meet its performance specifications or otherwise perform as intended. *Id.*

149. If the set screws and header for a cardiac device are designed in a way that the electrical lead could not be properly secured to the pulse generator and, thus, the device could not deliver life-saving therapy, then the device has malfunctioned in a manner which is likely to recur and likely to cause death or a serious injury.

150. As noted, immediately after the United States launch, BSC began receiving reports of adverse events. Hundreds of reports came in from BSC sales representatives in the field detailing problems with the defective set screws and the header, creating reporting obligations for BSC and, at some point, mandating a recall of the devices.

151. BSC attempted to minimize the defects, setting up flimsy excuses to avoid submitting Adverse Event Reports. Upper level management meetings were held and decisions were made in an attempt to "manage the noise" coming from the field.

152. Shortly after the U.S. launch of Cognis and Teligen, BSC's Cardiac Rhythm Management ("CRM") President, Fred Colen, instituted an unwritten policy that only patient-oriented issues would be reported to the FDA. If a patient needed a re-operation because of a faulty device, it should be reported to the FDA; however, if a doctor had a difficult time with

implantation (such as if the doctor could not get the lead secured due to burping or some other problem) and there were no significant patient complications, then the malfunction should *not* be reported to the FDA.

153. In addition to the President of CRM, the Relator can state that a number of different groups/individuals within CRM would have been involved in deciding which complaints from the field to report to the FDA as adverse events: the Vice President of Engineering, the Medical Safety Officer and others on the Adverse Events and Patient Safety Committees. Despite the involvement of all of these individuals and committees, the policy (of minimizing the reports having to do with the set screw/header defects) remained the same.

154. Further, many of the Adverse Event Reports that were in fact submitted to the FDA are misleading because they failed to mention the set screw design defect when in fact BSC knew about the design defect, *i.e.*, misleading by omission. Many of the Adverse Event Reports for incidents involving Cognis and Teligen were very likely related to the set screw/header defects, yet the Reports misleadingly omit the cause of the problems, a description of the event, any additional narrative information, and the results of any evaluation of the devices, all in violation of BSC's MAUDE reporting obligations. *See* Section XII.D. below for representative examples of misleading Adverse Event Reports.

VIII. BSC REDESIGNED AND REENGINEERED THE DEFECTIVE DEVICES AND CONTINUED TO MISLEAD THE FDA WHILE DOING SO

A. BSC Redesigned and Reengineered the Set Screw/Header Configuration

155. BSC knew from its experience with the European launch that the defective set screw/header configuration needed to be redesigned and reengineered.

156. Thus, long before it submitted a re-designed set screw/header (in February 2009), BSC internally worked on a redesigned and reengineered version of the devices to fix the set screw/header defects.

157. Internally, BSC referred to its redesigned and reengineered version of Cognis and Teligen as "V2" (Version 2). Version 2 fixed the set screws/header defects. Publicly and to the FDA, however, BSC did not refer to the corrected devices as "Version 2," but rather treated the redesign and reengineered version as a "continuing product improvement," while simultaneously failing to alert physicians, patients or the FDA regarding the true significance of the defects.

158. On February 18, 2009, BSC submitted PMA Supplements for Cognis (PMA Number P010012/Supplement Number 203) and Teligen (PMA Number 960040/Supplement Number 190) seeking approval for, *inter alia*, "modifications" to the set screw design. The PMA Supplements were submitted pursuant to the "Real-Time Process" which is only for "*minor* change that can be expected within a product line." Food and Drug Administration, *Real-Time Premarket Approval Application (PMA) Supplements* (Apr. 28, 2006), *available at* https://www.fda.gov/MedicalDevices/ucm089602.htm#f5 (emphasis added). BSC chose the Real Time Process rather than the 180-day process as would be required for design changes affecting the safety and effectiveness of the device, as this change clearly did. 21 C.F.R. § 814.39(a)(6).

159. Had these February 2009 PMA Supplements followed the law and disclosed to the FDA the severity and depth of the design defects inherent in Version 1 of the devices, the FDA would have recalled the "Version 1" devices, as it finally did in July 2009, once the FDA learned the truth about the design defects. Instead, the FDA continued to allow Version 1 of the devices to be marketed.

160. The FDA approved the Version 2 PMA Supplements on March 18, 2009 – without any required action as to the defective Version 1 devices – because the redesign purportedly made (and, it turns out, did make) the devices safer because the redesign corrected the defects. *See* Exhibits 3 and 4.

161. After BSC had re-designed the devices to fix the set screw/header defects in Version 2, BSC continued to conceal the defect pursuant to its FDA reporting obligations by submitting misleading reports which very effectively disguised the design defects. *See* Section XII.D. below for representative examples of misleading Adverse Event Reports.

B. BSC Continued to Sell Defective Devices While The Non-Defective Version 2 Devices Were Available

162. In or around late March 2009, BSC began selling the corrected Version 2 of Cognis and Teligen devices.

163. Instead of alerting physicians or patients about the defects in Version 1, or asking for the return of unused defective devices or issuing a recall, *BSC continued to sell the defective devices and allowed already-sold inventory to remain on hospital shelves for implantation in patients*.

164. The defective devices continued to be implanted into unsuspecting patients by uninformed physicians until July 2009, when the defective devices were finally recalled.

165. In terms of which customers – and consequently which patients – received the defective devices, BSC instructed its sales representatives to sell the Version 2 devices to customers based on the following ranking:

- First, to the customers (doctors and hospitals) who complained most about the old version or who had refused to implant the old version because of the problems related to the defective set screws;[2] and

- Second, to one sales region at a time over a 4 week period. The structure of the regional release of Version 2 was carefully orchestrated. The goal of the regional release was to make sure that customers who did not receive the updated version right away did not get upset with BSC because another customer in the same region had received the updated version.

166. Thus, Version 2 Cognis and Teligen devices were *not* initially made available to loyal customers who had continued to implant the devices despite problems with the set screws/header. For example, the hospital at which Relator works, Scripps Memorial Hospital in La Jolla, California was considered a loyal BSC customer and did not receive the new devices until over one month after they first become available. Physicians at Scripps and other hospitals continued to unwittingly implant the defective Cognis and Teligen devices into unknowing patients.

167. In this way, BSC endeavored to sell all of the remaining defective devices. In fact, some defective devices were taken from sales representatives' "trunk stock" and sold elsewhere in the United States to physicians and hospitals who were not high priorities to BSC.

168. There were no unique features to Cognis and Teligen which would make them preferable to the numerous other devices on the market at the time.

[2] BSC's Technical Services Department tracked which doctors and hospitals had had the most problems with the defective Cognis and Teligen devices and/or had stopped implanting the devices. Apparently, Duke University Hospital had had so many issues with the devices that it had stopped implanting BSC cardiac devices. Thus, it was one of the first customers to receive the Version 2 of the devices. Another customer to quickly receive the new devices was Dr. Nikolaos J. Tsiouris, an electrophysiologist from Las Vegas, Nevada who did a high volume of implants each month.

169. At all times, both before and after Version 2 Cognis and Teligen became available, there were numerous safe alternatives to the defective Cognis and Teligen devices to implant in patients. These included the competitor Medtronic's ICDs (Marquis, Virtuoso, Maximo, Secura and Virtuoso II which are all comparable to Teligen) and CRT-D devices (InSync II Marquis, InSync Sentry, InSync Maximo, Concerto, Consulta and Maximo II, all comparable to Cognis) and St. Jude Medical's ICDs (Current, and Atlas II) and CRT-D devices (Atlas II, Atlas II+, Epic, Epic II and Promote+).

170. Despite the ready availability of numerous safe alternative cardiac devices, BSC continued to sell the defective Cognis and Teligen devices to use up or "obsolete" its inventory. BSC required its sales representatives to continue to sell the defective devices. BSC fined any sales representative $2,500 per device for any expired devices the sales representative had not sold.

IX. THE SET SCREW/HEADER DEFECT WARRANTED AN FDA RECALL IN JULY 2009

171. A recall may be initiated if a medical device presents a risk of injury or is otherwise defective. 21 C.F.R. §§ 7.40, 7.45. A manufacturer may decide on its own initiative "to remove or correct a distributed product. . . . Such removal or correction will be considered a recall only if the [FDA] regards the product as involving a violation that is subject to legal action, e.g., seizure." 21 C.F.R. § 7.46(a).

172. The set screw/header defect was serious and dangerous enough to warrant the FDA to classify the removal of the devices as a recall. Importantly, the FDA's determined cause of the recall was "Device Design" of the Cognis and Teligen devices. Exhibits 5 and 6.

173. Specifically, on Friday, July 17, 2009, almost one year after the domestic launch of Cognis and Teligen, Boston Scientific "field personnel began retrieving devices containing the

original [defective] set screw system." BSC took the following actions regarding removal of the defective devices from the field:

> If needed a letter, dated 07/17/2009 was left with the hospital administrator letting them know that product has been collected for return to Boston Scientific Corporation. Replacement devices will be provided at no charge. If the field personnel was unable to contact the hospital in the time provided, a notification letter dated July 22, 2009 was sent via Federal Express to the hospital. This letter was directed to the EP Catheter Lab Manager with a cc to the Hospital Risk Manager, Hospital Administrator and Purchasing and Central Supply. The letter asked that *the affected devices not be implanted* and to contact their local representative for pick-up and return. The firm will replace the affected devices.

Exhibits 5 and 6 (emphasis added).

174. As discussed above, BSC had begun to sell "Version 2" of the devices a few months before, so at this time, only a limited number of defective "Version 1" devices were still in the field (and not yet implanted in patients). For the most part, by July 2009, hospitals in the United States were implanting the corrected Version 2 Cognis and Teligen devices.

175. Thus, at the time BSC "voluntarily" retrieved the defective devices, only approximately 45 Cognis devices and 104 Teligen devices were on hospital shelves in about 19 states, District of Columbia and Puerto Rico. Stated differently, BSC's campaign to conceal the defects in the original versions of Cognis and Teligen was a huge success, and had minimal financial impact on the company.

176. After investigation, the FDA subsequently classified Boston Scientific's removal of the devices as a Class II recall of Cognis and Teligen devices and determined that the cause for the recall was "Device Design." The devices "containing the original set screw system" were recalled:

> Boston Scientific Cardiac Rhythm Management retrieved devices that could be subject to a *potential for acute non-secure lead*

> *connections* when implanted. Nonsecure lead connections can manifest as high impedence, or lead electrogram artifacts resulting in oversensing and/or inappropriate deliver of therapy.

Exhibits 5 and 6 (emphasis added).

177. Once the devices were recalled, they were no longer being implanted by physicians and, thus, physicians and hospitals were no longer seeking reimbursement. Thus, CMS would not have been presented with reimbursement requests for "Version 1" of Cognis and Teligen post-recall.

178. BSC tried to limit the impact and scope of the recall in another material respect. Prior to the July 2009 recall, BSC informed the FDA that it believed any problems with the defective Cognis or Teligen devices already implanted in patients would manifest within 30 days of implant. Through its efforts, BSC was able to convince the FDA to limit the recall only to devices implanted less than 30 days before the recall.

179. To Relator's knowledge, there is no medical or scientific support that the defects would manifest themselves within 30 days. To the contrary, Relator's evidence demonstrates that the defects remained past this arbitrary 30-day window.

180. Specifically, Relator had at least two patients who experienced problems with the Cognis/Teligen device most likely attributable to the set screw/header more than a year after implant (see Section X. below).

X. PATIENT HARM KNOWN TO THE RELATOR

181. Relator has firsthand knowledge and is able to testify as to patients who were injured or underwent re-operation due to the defective Cognis and Teligen devices.

182. On January 28, 2009, Relator operated on a 79 year-old Medicare patient at Scripps Memorial Hospital in La Jolla, California. The patient already had a Cognis/Teligen device and

leads in his chest, but needed new leads attached to the device. After a successful procedure, which included testing of induced ventricular fibrillation, the patient was transferred to a hospital room.

183. While recuperating overnight, the patient received a painful, inappropriate shock from the Cognis/Teligen device. The device was therefore inactivated until a repair could be initiated. While inactivated, the device could no longer provide life-saving therapy. The patient was dependent on hospital-provided monitoring and the availability of staff should life-saving therapy be needed. Relator concluded that there was a problem with the device and commented in his operative notes: "The noise [problem with the lead causing the inappropriate shocks] could not be resolved fro[m] a software standpoint, suggesting that the lead header connection was not adequate."

184. The next morning, the patient was taken back to surgery for another operation to evaluate the problem with the device's set screw. As shown from Relator's operative notes dictated after the surgery on or around January 29, 2009, the problem with the patient receiving inappropriate shocks was due to BSC's set screw/header configuration. As he observed at the time, the set screw/header on the device allowed the lead to detach from the header even though the set screw was screwed firmly down:

> The set screw was completely screwed down as firmly as possible. However, with firm pressure, the right ventricular lead could be pulled out of the header. Looking down the barrel of the header, there was no screw visible suggesting that the abnormality described with this particular Boston Scientific header was a problem.

185. In order to fix the problem, Relator did the following:

> The screw was backed out and reset in a perpendicular fashion so that looking down the barrel, you could see the screw entering the header. It was backed out again, the lead reinserted and secured down. The lead could no longer be pulled out.

186. Relator's technique fortunately resolved the problem. As he concluded in his notes:

> [T]he header issue . . . appears to be resolved. This unlikely will recur, and did not warrant replacement generator as the set screw could be visualized to be now perpendicular.

187. Additionally, at least two of Relator's patients who had implanted Teligen devices each suffered inappropriate shocks from the devices more than a year after implant, most likely due to the set screw/header problem. During follow-up visits with each patient, the patients' electrograms revealed electrical "noise" due to oversensing of the Teligen devices which caused the inappropriate shocks. These patients continue to be periodically monitored and have not yet required reoperation, as the shocks have not recurred and the batteries in their devices do not need (yet) to be replaced. One of these two patients has Medicare and, thus, CMS paid for the initial implantation of the defective device.

XI. BOSTON SCIENTIFIC KNOWINGLY CAUSED THE SUBMISSION OF FALSE CLAIMS FOR REIMBURSEMENT TO THE GOVERNMENT

A. BSC Caused Hospitals and Physicians to Unwittingly and Falsely Certify that Implanting Cognis and Teligen was Medically Reasonable and Necessary

188. Notwithstanding approval from the FDA to market a medical device, the device must be "reasonable and necessary" for the diagnosis and treatment of illness or injury to be reimbursed by government healthcare programs. *See, e.g.,* 42 U.S.C. § 1395y(a)(1)(A); *see also* 10 U.S.C. § 1079(a)(13).

189. Similarly, any services which are incident to medically unnecessary care are not reimbursable. 42 C.F.R. § 405.207 ("[P]ayment is not made for medical and hospital services that are related to the use of a device that is not covered because CMS determines that the device is not 'reasonable' and 'necessary' . . . or because it is excluded from coverage for other reasons.").

190. Hospitals submit claims for reimbursement to Medicare, most Medicaid Programs and TRICARE on CMS Form 1450 (Form UB-04) or the electronic equivalent. On the back of

the claim form it states that "[s]ubmission . . . constitutes certification that the billing information shown on the face hereof is true, accurate and complete" and also states, for TRICARE purposes, that the services provided were "medically necessary and appropriate for the health of the patient."

191. Physicians submit claims for professional services on CMS Form 1500 or the electronic equivalent, which sets forth both the code describing the patient's diagnosis and the procedure codes utilized during the patient's stay. On the claim form, the physician certifies that the care provided was "medically indicated and necessary to the health of the patient...." and that the provided information is "true, accurate and complete."

192. Relator, a nationally known electrophysiologist with more than 30 years of experience, estimates that two-thirds of defibrillator implants in the United States are paid for by government payors. As a former BSC employee, Relator can state that BSC knew that hospitals and physicians would bill the government for implanting medically unnecessary and medically unreasonable devices and surgeries.

193. BSC further knew that these hospital and physicians would make false certifications to the government per BSC's knowledge of the billing process and the medical necessity and reasonableness certifications on the reimbursement forms referenced immediately above.

194. Causing another to falsely certify compliance with the law incurs liability under the FCA. *United States ex rel. Hutcheson v. Blackstone Medical, Inc.*, 647 F.3d 377, 390 (1st Cir. June 1, 2011) ("[U]nlawful acts by non-submitting entities may give rise to a false or fraudulent claim even if the claim is submitted by an innocent party); *see also United States v. Rivera*, 55 F.3d 703, 710-712 (1st Cir. 1995) (stating that a "false claim may be presented through an innocent third party.") (citations omitted).

195. Relator can state that at the time that the defective Cognis and Teligen devices were on hospital shelves, there were numerous safe alternatives to the defective BSC devices including those manufactured by competitors Medtronic and St. Jude Medical.

196. Relator can further state that had he known the truth about the set screw/header defects in Cognis and Teligen, he would not have implanted these devices in his patients because it was not medically reasonable or medically necessary to do so.

197. In terms of specific false claims, Relator can further state that he implanted the defective devices from the time of launch until approximately July 2009. Relator is familiar with his own patients, and their form of insurance. Relator can stated that he implanted the defective devices in approximately 180 of his own Medicare and other government health insurance patients, thus unwittingly causing the submission of approximately 180 false claims to government healthcare programs.

198. On information and belief, thousands of other physicians nationwide unwittingly submitted medically unreasonable and medically unnecessary claims in the same manner.

199. All such claims violated the FCA, regardless of whether a specific device actually malfunctioned, because the design defect rendered the devices medically unnecessary and medically unreasonable for the intended function of maintaining appropriate heart rhythms in cardiac patients.

B. BSC Caused Hospitals and Physicians to Unwittingly Submit False Claims for Defective Devices

200. Notwithstanding approval from the FDA to market a medical device, a device which is defective is not reimbursable. In fact, defective products were a primary reason the FCA was originally enacted:

> [T]he civil False Claims Act, originally known as…Lincoln's Law, was enacted when allegations of fraud, defective weapons, and illegal price-gouging of the

> Union Army arose during the Civil War." "The need for the qui tam action was predicated on the gravity of the consequences that resulted when unscrupulous contractors supplied inferior goods to the Union Army."

Civil False Claims and Qui Tam Action, Boese, J., Fourth Edition, Vol. 1, §§1-11

201. A military contractor who knowingly sells a defective weapon to the government has presented a false claim for payment. The defect is the falsity: the government believes it is purchasing a weapon that works, while the contractor knows that the weapon is defective.

202. This concept has since been applied to fraud related to FDA approval.

203. In *United States ex rel. Nargol v. Depuy Orthopaedics, Inc*., 865 F.3d 29 (1st Cir. 2017), the relator made a claim for a defective device which was functionally equivalent to the claim here:

> We now arrive at Relators' principal theory of fraud raised on this appeal: that DePuy often sold to health care providers a defectively manufactured product that materially differed from the device the FDA approved . . . This theory –that DePuy got FDA approval for a device and then palmed off a defective version of that device both directly on the government itself and on unsuspecting doctors and patients, who then submitted claims for payment to unsuspecting government payors – is a theory of actionable misconduct under the FCA.

Id., at 37.

204. Similarly, in *United States. ex rel. Campie v. Gilead Sciences, Inc.*, 862 F.3d 890 (9th Cir. 2017), the Department of Justice argued that "a claim can be 'false' when the government was not provided the product that it bargained for. Accordingly, when determining if the claim was false, the proper inquiry examines whether the product supplied was sufficiently tainted or defective such that it was not what it was represented to be." *Gilead, Amicus Brief of the United States*, ECF No. 20, at 23-24.

205. The *Gilead* court agreed:

> Additionally, as we have previously explained, the False Claims Act "was enacted during the Civil War with the purpose of forfending widespread fraud by government contractors who were submitting inflated invoices and shipping faulty goods to the government." *Hopper*, 91 F.3d at 1265–66. That core purpose would not be served if a defendant could escape liability for delivering nonconforming goods merely because the goods retained some value or in the absence of a bilateral contract. It is fraudulent conduct that gives rise to liability, regardless of whether the underlying relationship is based in contract, regulation, or statute. *Nat'l Wholesalers*, 236 F.2d at 950. As we have previously held, the provision of nonconforming goods can be a basis of liability under the False Claims Act. *See Hopper*, 91 F.3d at 1266 (citing *Aerodex* for proposition that "[False Claims Act] actions have also been sustained under theories of supplying substandard products or services).

862 F.3d at 900-901.

206. Thus, a device manufacturer who knowingly sells a defective cardiac device to a hospital, knowing that the hospital and physician will bill the government for implanting the device (as approximately two-thirds of defibrillator implants are paid for by government payors), has caused a false claim to be presented. The falsity is the same: the government believes it is paying for a cardiac device that works, while the device manufacturer knows that the device is defective.

207. And there can be no question that these devices were defective to the point that the government would not have paid for the devices had it known the truth. Indeed, once the truth about Cognis and Teligen became (partially) known, the devices were recalled.[3]

208. All such claims for the devices were false, regardless of whether a specific device actually malfunctioned, because the design defect rendered the devices unreliable and not suitable for the intended function of maintaining appropriate heart rhythms in cardiac patients.

[3] Further, medical devices that lack approval from the FDA are not reimbursable. *See* 42 C.F.R. § 411.15(o); 42 C.F.R. § 405.211(C).

C. BSC Caused Hospitals and Physicians to Unwittingly Submit False Claims for Misbranded Devices

209. Notwithstanding approval from the FDA to market a medical device, a device manufacturer is prohibited from introducing a medical device into interstate commerce that is misbranded. 21 U.S.C. §331(a).

210. A medical device is misbranded if *it is hazardous to patient health when used as directed in its labeling*. 21 U.S.C. §352(j).

211. A medical device is also misbranded if its labeling is false or misleading. 21 U.S.C. §352(a).

212. The FDA labels for these devices were false and/or misleading because they did not contain adequate instructions for use. Indeed, although Boston Scientific generated and circulated various "workaround" documents which it hoped would ameliorate the design defects inherent in the devices, those documents – including, for example, the "Closer Look" documents referenced above – were not part of the FDA labels for these devices.

213. As approximately two-thirds of defibrillator implants are paid for by government payors, BSC knew that hospitals and physicians would bill the government for implanting misbranded Cognis and Teligen devices.

214. These devices were misbranded to the point that the government would not have paid for the devices had it known the truth. Indeed, once the truth about Cognis and Teligen became (partially) known, the devices were recalled.[4]

[4] As noted above, medical devices that lack approval from the FDA are not reimbursable. *See* 42 C.F.R. § 411.15(o); 42 C.F.R. § 405.211(C).

D. BSC Fraudulently Induced the FDA Approval of Cognis and Teligen

215. Courts have repeatedly held that liability for fraud in the inducement is established when eligibility to receive funds under a government program was procured by lies or other misleading actions. *United States ex rel. Miller v. Weston Educ., Inc.*, 840 F.3d 494 (8th Cir. 2016); *In re: Baycol Prods. Litig.*, 732 F3d 869 (8th Cir. 2013). In these cases, liability attaches "to each claim submitted to the government under a contract, when the . . . extension of government benefit was originally obtained through false statements or fraudulent conduct." *See, e.g., United States ex rel. Hendow v. University of Phoenix*, 461 F.3d 1166, 1173 (9th Cir. 2006), *cert. den.*, 550 U.S. 903 (2007)(citations omitted).

216. More specific to this case, an FCA action may be based on a theory of fraud-on-the-FDA. *See United States ex rel. Brown v. Pfizer, Inc.*, 2016 WL 807363, *8-10 (E.D. Pa. 2016) (relator's allegations that defendant submitted false and misleading application for approval of a drug to the FDA were upheld as sufficient under the False Claims Act); *United States ex rel. Krahling v. Merck & Co., Inc.*, 2014 WL 4407969, *6-7 (E.D. Pa. 2014)(finding that relator's fraud-on-the-FDA FCA case withstood defendant's motion to dismiss). FCA liability may be grounded in "omissions to regulatory agencies, discretion in agency action, or violations of regulations." *Id.* (citation omitted).

217. Here, Boston Scientific knowingly provided misleading and incomplete information to the FDA prior to the approval of Cognis and Teligen. Specifically, and as discussed in more detail above, BSC knew that Cognis and Teligen suffered from serious malfunctions involving the electrical connection between the leads and the pulse generator, yet they failed to submit an amendment to its pending Pre-Market Approval Supplement to the FDA, alerting the Agency as to the problems encountered in Europe and elsewhere.

218. Had the FDA known the truth, it would not have approved the devices. This is evidenced by the subsequent recall of Cognis and Teligen.

E. BSC Continued to Defraud the FDA after Approval

219. After the FDA approved the devices in May 2008, BSC continued to deceive the FDA. Specifically, from May 2008 through July 2009 (when the devices were recalled in the United States), BSC made a series of false and misleading statements and omissions to the FDA regarding the devices including the following:

- BSC failed to notify the FDA through submitting a PMA Supplement when it revised the Cognis and Teligen implant instructions for physicians as an attempt to remedy the defect;
- BSC misleadingly minimized and delayed reporting adverse event reports regarding Cognis and Teligen to the FDA and many of the reports that were submitted were vague and omitted material information regarding the defect;
- BSC designed, manufactured and launched corrected Cognis and Teligen devices ("Version 2") in March 2009 and BSC still failed to initiate a recall of the defective "Version 1";
- BSC submitted misleading PMA Supplements regarding Version 2 of the devices, failing to disclose that the existing Version 1 devices had design defects that created serious risks of injury or death;
- BSC misled the FDA about the severity of the defect leading up to the eventual Class II recall of the devices in July 2009.

220. Had the FDA known the truth, it would have recalled the devices at an earlier time. This is evidenced by actual recall of Cognis and Teligen, which occurred after the FDA learned enough about the devices to take action.

F. Specific False Claims

221. Representative examples of false claims which BSC caused to be submitted to the government for payment are included in Exhibit 7. Exhibit 7 is a list of representative patients who were implanted with the defective Cognis or Teligen devices from September 2008 through

February 2009 at Scripps Memorial Hospital in La Jolla, California. The Exhibit details the date of the Cognis/Teligen surgery, the name of the electrophysiologist performing the surgery, whether the surgery was performed on an in-patient or out-patient basis, the patient's primary insurance (*i.e.*, Medicare or Medicaid) and the amount of reimbursement from Medicare/Medicaid that the hospital received for the surgery.

G. BSC Caused Significant Financial Harm to the Government

222. Throughout the relevant time periods specified herein, defective and misbranded Cognis and Teligen devices were implanted in patients across the United States and were paid for by Medicare, Medicaid and other federal health care programs. By knowingly selling these defective cardiac devices to hospitals and causing hospitals to bill the government for non-reimbursable products, Boston Scientific caused the government to pay for devices and services which the government did not receive. Moreover, when the devices affirmatively malfunctioned, *e.g.*, when it was discovered that the devices were either oversensing or undersensing, the defects triggered additional procedures, such as re-operation, and other consequential damages due to patient harm.

223. As to the potential quantification of damages, the evidence obtained by Relator indicates that the defective Cognis and Teligen devices were implanted in patients in the United States from approximately 2008 until they were recalled in July 2009. It is estimated that during this time, approximately 30,000 defective devices were implanted in patients. Approximately two-thirds of those implants were paid for by the government. With the average government reimbursement of $35,000 for a Cognis or Teligen device surgery (and much more, up to $50,000 for reimbursement to teaching hospitals), Boston Scientific caused the government to suffer approximately $1 billion in damages.

XII. BSC'S SPECIFIC FALSE AND MISLEADING STATEMENTS BY OMISSION TO THE FDA

A. Pleading Fraud by Omission with Particularity in Satisfaction of Rule 9(b)

224. Federal Rule of Civil Procedure 9(b) requires that "[i]n alleging fraud . . . a party must state with particularity the circumstances constituting fraud." Generally speaking, the "circumstances constituting fraud" that must be pled "include such matters as the time, place and contents of false representations, as well as the identity of the person making the misrepresentation and what was obtained or given up thereby." *Bennett v. Berg*, 685 F.2d 1053, 1062 (8th Cir. 1982) (internal quotation marks omitted).

225. Fraud claims (including FCA claims) may be committed by an affirmative misrepresentation *or omission*. *See Universal Health Servs., Inc. v. United States*, 136 S. Ct. 1989, 1999 (2016) ("[T]he False Claims Act encompasses claims that make fraudulent misrepresentations, which include certain misleading omissions.").

226. Unlike affirmatively fraudulent statements like those addressed by the Eight Circuit in *Bennett*, misleading statements by omission "cannot be described in terms of the time, place, and contents of the misrepresentation or the identity of the person making the misrepresentation. " *Flynn v. Everything Yogurt*, 1993 WL 454355, at *9 (D. Md. Sept. 14, 1993). Thus, in cases involving fraudulent omissions, a "[p]laintiff is unable to specify the time and place because no act occurred." *Weaver v. Chrysler Corp.*, 172 F.R.D. 96, 101 (S.D.N.Y. 1997); *see also Daher v. G.D. Searle & Co.*, 695 F. Supp. 436, 440 (D. Minn. 1988) ("'[M]alicious silence' is, by its very nature, difficult to plead with particularity.").

227. Put differently, "[l]ike Sherlock Holmes' dog that did not bark in the night, an actionable omission obviously cannot be particularized as to 'the time, place, and contents of the false representations' or 'the identity of the person making the misrepresentation.'" *Bonfield v.*

AAMCO Transmissions, Inc., 708 F. Supp. 867, 875 (N.D. Ill. 1989). As one court explained, "[r]equiring a plaintiff to identify (or suffer dismissal) the precise time, place, and content of an event that (by definition) did not occur would effectively gut . . . laws prohibiting fraud-by-omission." *In re Whirlpool Corp. Front-Loading Washer Prod. Liab. Litig.*, 684 F. Supp. 2d 942, 961 (N.D. Ohio 2009).

228. In light of the inherent difficulty in pleading identifying details of an omission, various courts have held that the "particularity requirements are less strictly applied with respect to claims of fraud by concealment." *Shaw v. Brown & Williamson Tobacco Corp.*, 973 F. Supp. 539, 552 (D. Md. 1997); *see also Woodard v. Labrada*, 2017 WL 3309765, at *8 (C.D. Cal. July 31, 2017) ("A fraud by omission or fraud by concealment claim can succeed without the same level of specificity required by a normal fraud claim.") (internal quotation marks omitted); *Hilkene v. WD-40 Co.*, 2005 WL 3050434, at *2 (D. Kan. Nov. 14, 2005) (agreeing that "Rule 9(b) cannot be rigidly applied to the alleged omissions in this case"); *Asghari v. Volkswagen Grp. of Am., Inc.*, 42 F. Supp. 3d 1306, 1325 (C.D. Cal. 2013) ("When a claim rests on allegations of fraudulent omission, . . . the Rule 9(b) standard is somewhat relaxed because a plaintiff cannot plead either the specific time of [an] omission or the place, as he is not alleging an act, but a failure to act.") (internal quotation marks omitted); *Schwartz v. Pella Corp.*, 2014 WL 7264948, at *6 (D.S.C. Dec. 18, 2014) ("[M]any courts have recognized the difficulty of applying Rule 9(b)'s particularity requirement to fraudulent concealment or omission claims, and have instead applied a relaxed, less formulaic version of the rule.").

229. Given the incompatibility between the customary "who, what, why, when and where" requirements of Rule 9(b) and pleading fraudulent omissions, courts have fashioned

different tests to determine whether fraudulent omission claims are pled with the requisite particularity. For example:

- "In order to comply with the pleading requirements of Rule 9(b) with respect to fraud by omission, a plaintiff usually will be required to allege the following with reasonable particularity: (1) the relationship or situation giving rise to the duty to speak, (2) the event or events triggering the duty to speak, and/or the general time period over which the relationship arose and the fraudulent conduct occurred, (3) the general content of the information that was withheld and the reason for its materiality, (4) the identity of those under a duty who failed to make such disclosures, (5) what those defendant(s) gained by withholding information, (6) why plaintiff's reliance on the omission was both reasonable and detrimental, and (7) the damages proximately flowing from such reliance." *Breeden v. Richmond Cmty. Coll.*, 171 F.R.D. 189, 195 (M.D.N.C. 1997)
- "In cases where the alleged fraud consists of an omission and the Plaintiff is unable to specify the time and place because no act occurred, the Complaint must still allege what the omissions were, the person responsible for failing to disclose, the context of the omission and the manner in which it misled Plaintiff, and what Defendant obtained through the fraud." *Weaver v. Chrysler Corp.*, 172 F.R.D. 96, 101 (S.D.N.Y. 1997).
- "[O]ther districts have recognized that 'fraud by omission' claims need not be pled with quite the same degree of specificity required of 'affirmative fraud' claims" but held that "even in a fraud-by-omission case, a plaintiff must show that the defendant had a duty to disclose but did not do so." *Sanford v. Maid-Rite Corp.*, 2014 WL 1608301, at *12 (D. Minn. Apr. 21, 2014) (internal quotation marks omitted), *rev'd and remanded on other grounds*, 816 F.3d 546 (8th Cir. 2016).

B. BSC's False and Misleading Statements by Omission to the FDA Prior to the FDA Approval of Cognis and Teligen in May 2009

230. The FDA approvals for Cognis and Teligen are based on original PMAs submitted to the FDA by Guidant (BSC's predecessor).

231. Specifically, on August 20, 1996, Guidant submitted a PMA to the FDA for Ventak, an implantable cardioverter defibrillator. The Original PMA Number is P960040. This is the original PMA on which the FDA's approval of the Teligen device was based. On July 18, 1997, the FDA approved the Original PMA for Ventak. Exhibit 8.

232. And, on February 27, 2001, Guidant submitted a PMA to the FDA for Contak, a cardiac resynchronization therapy defibrillator. The Original PMA Number is P010012. This is the original PMA on which the FDA's approval of the Cognis device was based. On May 2, 2002, the FDA approved the Original PMA for Contak. Exhibits 9 and 10.

233. Thus, the FDA approved the Cognis and Teligen predicate devices – Contak and Ventak – as safe and effective for their indicated uses. Exhibits.8, 9 and 10.

234. After approval of a PMA, an applicant must "submit a PMA Supplement for review and approval by the FDA before making a change affecting the safety or effectiveness of the devices for which the applicant has an approved PMA". 21 C.F.R. § 814.39(a); *see also* Exhibit 10 (Contak approval stating that as one of the conditions of approval, the FDA advised Guidant that "[b]efore making any change affecting the safety or effectiveness of the device, [it must] submit a PMA supplement for review and approval by FDA . . . ."). A 180-day PMA Supplement is for significant changes that affect the safety and effectiveness of the device, allowing the FDA up to 180 days to conduct an in-depth review before approval.

235. On December 7, 2007, BSC submitted 180-day PMA Supplements, Number 165 for Cognis and Number 155 for Teligen. Therefore, BSC made an internal determination that

PMA supplements 165 and 155 involved changes "affecting the safety or effectiveness of the devices for which the applicant has an approved PMA." 21 C.F.R. § 814.39(a).

236. At least one of the reasons for these PMA Supplements was the design change in the devices with regard to the set screw/seal plug/header configuration. These PMA Supplements relied on and incorporated the safety and effectiveness information from the original PMAs for the Contak and Ventak devices. Further, as noted, the FDA will not approve a PMA supplement unless it establishes that the proposed changes to the device will not render it either unsafe or ineffective. Therefore, BSC's PMA Supplements 165 and 155 contained information and representations from BSC affirmatively vouching for the safety and effectiveness of the devices.

237. Although Relator can state that PMA Supplements 165 and 155 contained information and representations from BSC regarding the safety and effectiveness of the redesigned devices, Relator does not have that specific safety and effectiveness data because those supplements are shielded from public review. O'Reilly Decl. ¶ 10; Filbert Decl. ¶¶ 5-6.

238. The Boston Scientific employees involved with interacting with the FDA with respect to approval of Cognis and Teligen include the following individuals:

- **Fred Colen**, President Cardiac Rhythm Management (CRM)
- **Arjun D. Sharma**, M.D., FACC, Vice President, Patient Safety
- **William F. McConnell, Jr.**, Senior VP, Sales, Marketing, Business Strategy, CRM[5]
- **Agneal Daigle**, Regulatory Affairs
- **Cori Ragan**, Regulatory Affairs
- **Ron Thompson**, Regulatory Affairs
- **Jim Gilkerson**, DVM[6], Clinical Advisor

---

[5] He is also a member of BSC's Field Action Committee that ordered retrieval of the Cognis and Teligen devices from the field in July 2009.

[6] Doctor of Veterinary Medicine who ran BSC's animal lab and coordinated animal teaching and research.

239. The PMA Supplements, and the information and representations noted above, were then reviewed by the designated FDA product review team. O'Reilly Decl. ¶ 7. A typical product review team covers a type of medical device and often includes an engineer, a technical advisor skilled in the particular area of development, an experienced FDA staff "paper flow" person and where appropriate, a part-time physician or surgeon, with additional support as needed. *Id.*

240. The FDA product review team who evaluated the Cognis and Teligen PMA Supplement applications included Scientific Reviewers James Cheng and Doris Terry.

241. While the Cognis and Teligen PMA Supplements were being reviewed by the FDA and still pending, BSC began a market launch of the devices in Europe in February 2008. In late February 2008, physicians in Europe began implanting the Cognis and Teligen devices in patients. Initially, physicians in six different countries and 14 hospitals performed 40 implants of the devices. This was the beginning of the launch in Europe and was expanded throughout the Winter and Spring of 2008.

242. During that time, BSC began receiving reports of problems with the devices from Europe, including problems with the set screw/header design.

243. In response to the complaints of set screw design malfunctions emanating from Europe about the devices, BSC dispatched Sumi Dahm, head of the engineering team responsible for Cognis and Teligen, and members of his team, to investigate and deal with the complaints, including problems with the design of the set screw/header configuration.

244. In connection with this experience in Europe, BSC's engineering team developed coaching and implant technique changes to the process of attaching the leads to the set screw/header design featured on the just-released Cognis and Teligen devices. These implant

technique changes were not a real fix for the design problem, but rather were "workarounds" or stop-gap measures.

245. Boston Scientific should have filed amendments to the Cognis and Teligen PMA Supplements (P010012/S165 for Cognis and P960040/S155 for Teligen) with the FDA to alert the FDA about the new safety information about the devices' set screw/header design learned through the European launch.

246. BSC's failures to thus inform the FDA's product review team were misleading statements by omission.

247. These omissions simultaneously rendered false the affirmative statements in the PMA Supplements regarding the safety and effectiveness of the devices because the devices were not safe or effective. They were unsafe because they were subject to fatal failure and could cause inappropriate shocks. They were ineffective because they were subject to fatal failure.

248. Stated differently, the PMA Supplements (and Original PMAs on which the Supplements relied) submitted in December 2007 were thereby rendered false and misleading in that they represented to the FDA that the devices were safe and effective for the treatment of patients with certain cardiac conditions, when in fact the devices were not safe or effective if the set screw/header malfunctioned. BSC thus failed to meet its obligations to advise the FDA product review team of material problems with the devices under consideration, and instead left the FDA review team thinking that the initial claims of safety and effectiveness in the PMA Supplements were reliable and accurate.

249. Without the additional information about Cognis and Teligen which BSC learned from the European launch, the FDA approved the devices on May 8, 2008 for sale in the United States. *See* Exhibits 1 and 2.

250. As noted, the failure to file Amendments to the pending PMA Supplements for Cognis and Teligen regarding the problems with the set screw/header encountered in Europe would be considered material to the FDA. Specifically, as noted by Relator's expert, by failing to alert the FDA about the problems encountered in Europe, "BSC misled the FDA's product review team." O'Reilly Decl. ¶ 11. He further stated:

> FDA product review team decisions are focused on disclosure and analysis of risks. . . . It is the obligation of the sponsor to deliver risk data to the applicable FDA review team, and BSC should have delivered the risk information outlined in the complaint to the FDA product review team that BSC knew was considering its Supp-PMAs for Cognis and Teligen.
>
> It is not sufficient to merely make a routine filing of the FD3500A forms for entry into the MAUDE data bases as part of that system's aggregation of all device experiences.

Id. ¶¶ 11-12.

251. Relator's expert ultimately concluded: "If the information in the complaint is true, reporting the risk information outlined in the complaint to the CDRH's product review team *would have delayed approval of the Supp-PMAs at issue, and is likely to have led to their denial*. Id. ¶ 13 (emphasis added).

252. Although the devices were not launched in the United States until almost three months later, BSC still did not fully disclose the extent of the problems to the FDA prior to selling the devices in the U.S.

253. It should be noted that the specific original PMAs (for Contak and Ventak) and the PMA Supplements for Cognis (S165) and Teligen (S155) are not available to the public prior to approval. 21 C.F.R. § 814.9; *see also* O'Reilly Decl. ¶ 10. After an approval order, the "PMA file" is made public, 21 C.F.R. § 814.9, however the "general public, including [Relator], cannot receive access to its contents without either (1) consent by the submitting company, or (2) awaiting

the very slow review and selective deletions by the DIOP staff inside FDA, after which the portions which FDA deems to be disclosable can be released." O'Reilly Decl. ¶ 10. To date, specifically, the FDA has not made public the safety and effectiveness data BSC presented to the FDA regarding Cognis (S165) and Teligen (S155). Filbert Decl. ¶ 6.

C. BSC's False and Misleading Statements by Omission to the FDA Post-Launch

254. As discussed above in Sections VII (BSC Continued to Knowingly Mislead the FDA During the United States Launch of Cognis and Teligen) and VIII (BSC Redesigned and Reengineered the Defective Devices and Continued to Mislead the FDA While Doing So), Boston Scientific continued to mislead the FDA after the launch of Cognis and Teligen in the United States.

255. Despite knowledge of the set screw/header defects learned in Europe prior to the U.S. market launch and despite hundreds of complaints from the field post-launch, BSC failed to notify the FDA of design defects inherent in the devices that created risks of injury or even death.

256. Instead, long before February 2009, BSC began an internal effort to develop redesigned and reengineered versions of the devices to fix the set screw/header defects.

257. Internally, BSC referred to its redesigned and reengineered version of Cognis and Teligen as "V2" (Version 2). Version 2 fixed the set screws/header defects. Publicly and to the FDA, however, BSC did not refer to the corrected devices as "Version 2," but rather treated the redesign and reengineered version as a "continuing product improvement," while simultaneously failing to alert physicians, patients or the FDA regarding the true significance of the defects.

258. Despite knowing about the design defects and despite working internally to fix them, BSC continued to mislead the FDA by omission by not telling the FDA the full truth about the defects.

259. Instead, BSC's misleading conduct continued. Specifically, on February 18, 2009, BSC submitted PMA Supplements for Cognis (PMA Number P010012/Supplement Number 203) and Teligen (PMA Number 960040/Supplement Number 190) seeking approval for, *inter alia*, "modifications" to the set screw design. The PMA Supplements were submitted pursuant to the "Real-Time Process" which is only for "*minor* change that can be expected within a product line." Food and Drug Administration, *Real-Time Premarket Approval Application (PMA) Supplements* (Apr. 28, 2006), *available at* https://www.fda.gov/MedicalDevices/ucm089602.htm#f5 (emphasis added). BSC chose the Real Time Process rather than the 180-day process as would be required for design changes affecting the safety and effectiveness of the device, as this change clearly did. 21 C.F.R. § 814.39(a)(6).

260. Had these February 2009 PMA Supplements followed the law and disclosed to the FDA the severity and depth of the design defects inherent in Version 1 of the devices, the FDA would have recalled the "Version 1" devices, as it finally did in July 2009, once the FDA learned the truth about the design defects. Instead, the FDA continued to allow Version 1 of the devices to be marketed.

261. The FDA approved the Version 2 PMA Supplements on March 18, 2009 – without any required action as to the defective Version 1 devices – because the redesign purportedly made (and, it turns out, did make) the devices safer because the redesign corrected the defects. *See* Exhibits 3 and 4.

D. BSC's Missing, Vague and Misleading Statements to the FDA, in the Form of Adverse Event Reports

262. Relator cannot specify which adverse events were not reported due to BSC's efforts to mislead the FDA, because the reports did not happen, thus there is no "who, what, where, when, and how" relating to these non-events.

263. Relator can, however, identify the who, what, where, when and how regarding how BSC executed its plan. Specifically, shortly after the U.S. launch of Cognis and Teligen, BSC's Cardiac Rhythm Management President, Fred Colen, instituted an unwritten policy that only patient-oriented issues would be reported to the FDA. If a patient needed a re-operation because of a faulty device, it should be reported to the FDA; however, if a doctor had a difficult time with implantation (such as if the doctor could not get the lead secured due to burping or some other problem) and there were no significant patient complications, then the malfunction should *not* be reported to the FDA.

264. Relator can further state that a number of different groups/individuals within CRM (in addition to Fred Colen) would have been involved in deciding which complaints from the field to report to the FDA as adverse events: the Vice President of Engineering, the Medical Safety Officer and others on the Adverse Events and Patient Safety Committees. Despite the involvement of all of these individuals and committees, the policy (of minimizing the Reports having to do with the set screw/header defects) remained the same.

265. In addition to this unlawful policy of minimizing reporting, many of the Adverse Event Reports that were in fact made by BSC were misleading by what they failed to say, *i.e.*, misleading by omission. These vague and misleading Adverse Event Reports contained some limited information indicating problems likely related to the defective set screw, yet the Report failed to clearly identify the set screw/header defect as causing the malfunction or injury or death. Failing to identify the set screw/header defect is a material omission to the FDA as well as a violation of the FDA regulations.

266. As set forth above, the regulations require particular information to be included in Adverse Event Reports, *inter alia*:

- Description of the event, including a discussion of how the device was involved and the nature of the problem;
- If the device was returned to the manufacturer, a summary of the evaluation performed on the device or an explanation as to why an evaluation was not performed;
- Any additional narrative.

21 C.F.R. § 803.52.

267. For example, there are many reports that indicate there were serious problems with the device, yet there is no narrative information provided about the cause of the reported problem. The reports simply state "high impedance" or "noise" or "undersensing" – all words that we now know point to the set screw defect. But these vague descriptions would lead to no such conclusion in 2008. Instead, they leave the reader with the impression that the company does not know why the adverse event occurred.

268. Further, there are numerous instances where the report clearly states that the explanted device had been returned to BSC and had been analyzed, yet there was still no information provided about the results of that analysis.

269. For example, MAUDE Report 2124215-2008-39196, submitted to the FDA on August 18, 2008, is materially misleading for the reasons which follow. Exhibit 11. The report indicates that the event in question occurred on August 5, 2008. Although the report indicates that the "Report Source" was BSC's "Company Representative," there is no narrative explaining what actually happened. For example, in the section titled "Event Type" it simply states "Injury." In the section titled "Patient Outcome," the report only states that the event "Required Intervention." But most importantly, even though the device in question was returned to BSC for evaluation on August 26, 2008, and even though the report states that the device was evaluated by BSC (presumably by the engineering and/or patient safety department(s)), the only description

provided in the section of the report titled "Device Problems" is the following quote: "High Impedance; Loose or intermittent connection."

270. Knowing what Relator and the Court know now, it is near certain the event was caused by the defects alleged in the Complaint. However, it would have been impossible for a reader in August 2008 to understand that this event – which involved patient injury and a surgical "intervention" – was caused by a set screw design defect uniform across all devices. This despite the fact that long before August 2008, BSC expressly knew about the design defects.

271. By way of further illustration, all of the Adverse Event Reports listed below were for incidents involving Cognis and Teligen and were very likely related to the set screw/header defects, yet the reports misleadingly omit the cause of the problems, a description of the event or any additional narrative information, all in violation of BSC's MAUDE reporting obligations. Further, all of these reports involve devices explanted from patients and returned to BSC for evaluation, but notably fail to include the results of those evaluations:

- MAUDE Report 2124215-2008-39341, submitted to the FDA on August 8, 2008, reported a Cognis device with a malfunction event. The report showed a "Connection error; High impedance; Mechanical issue." Exhibit 12

- MAUDE Report 2124215-2008-39530, submitted to the FDA on August 14, 2008, reported a Cognis device with a malfunction event. The report showed "Failure to shock or properly shock; Device displays error". Exhibit 13

- MAUDE Report 2124215-2008-39881, submitted to the FDA on August 25, 2008, reported a Cognis device with a malfunction event. The report showed a "Connection error; High impedance; Mechanical issue." Exhibit 14

- MAUDE Report 2124215-2008-40069, submitted to the FDA on August 29, 2008, reported a Cognis device with an injury event, which required patient intervention. The report showed "Failure to capture; High impedance; Loose or intermittent connection; Mechanical issue." Exhibit 15

- MAUDE Report 2124215-2008-39255, submitted to the FDA on August 6, 2008, reported a Teligen device with an injury event which required patient intervention. The report showed "High impedance; Mechanical issue." Exhibit 16

- MAUDE Report 2124215-2008-39330, submitted to the FDA on August 8, 2008, reported a Teligen device with an injury event, which required patient intervention. The report showed "Connection error; High impedance; Mechanical issue; Loss of threshold; Unknown (for use when the device problem is not known)" Exhibit 17

- MAUDE Report 2124215-2008-39392, submitted to the FDA on August 11, 2008, reported a Teligen device with an injury event, which required patient intervention. The report showed "Connection error; High impedance; Loss of threshold; Noise." Exhibit 18

- MAUDE Report 2124215-2008-39558, submitted to the FDA on August 15, 2008, reported a Teligen device with an injury event, which required patient intervention. The report showed "Difficult to insert; Mechanical issue; Failure to pace or properly pace." Exhibit 19

- MAUDE Report 2124215-2008-39806, submitted to the FDA on August 22, 2008, reported a Teligen device with an injury event, which required patient intervention. The report showed "High impedance." Exhibit 20

- MAUDE Report 2124215-2008-39872, submitted to the FDA on August 25, 2008, reported a Teligen device with an injury event, which required patient intervention. The report showed "High impedance." Exhibit 21

- MAUDE Report 2124215-2008-40040, submitted to the FDA on August 28, 2008, reported a Teligen device with a malfunction event. The report showed "High impedance." Exhibit 22

- MAUDE Report 2124215-2008-40045, submitted to the FDA on August 28, 2008, reported a Teligen device with a malfunction event. The report showed "Connection error, High impedance; Difficult to insert; Mechanical issue." Exhibit 23

272. By way of additional example, even after BSC had redesigned and reengineered the defective "Version 1" Cognis and Teligen devices to develop "Version 2," BSC continued to submit Adverse Event Reports with the FDA with incomplete and misleading information such that they continued to conceal the fact that Cognis and Teligen suffered from a design defect.

Further, these representative Reports all involve devices explanted from patients and returned to BSC for evaluation, but notably fail to include the results of those evaluations:

- MAUDE Report 2124215-2009-05112, submitted to the FDA on February 11, 2009, reported a Cognis device with an injury event. The report showed a "Connection error; High impedance; Mechanical issue." Exhibit 24

- MAUDE Report 2124215-2009-06721, submitted to the FDA on February 19, 2009, reported a Cognis device with an injury event. The report showed "Oversensing; Noise." Exhibit 25

- MAUDE Report 2124215-2009-06912, submitted to the FDA on February 6, 2009, reported a Teligen device with a malfunction event. The report showed "Failure to pace or properly pace; Failure to shock or properly shock; Unexpected therapeutic results; Device displays error message." Exhibit 26

- MAUDE Report 2124215-2009-05258, submitted to the FDA on February 12, 2009, reported a Teligen device with a malfunction event. The report showed "Loose or intermittent connection; Mechanical issue; Normal; Unknown (for use when the device problem is not known)." Exhibit 27

- MAUDE Report 2124215-2009-05257, submitted to the FDA on February 12, 2009, reported a Teligen device with a malfunction event. The report showed "Loose or intermittent connection; Mechanical issue; Unknown (for use when the device problem is not known)." Exhibit 28

- MAUDE Report 2124215-2009-04115, submitted to the FDA on February 13, 2009, reported a Teligen device with an injury event. The report showed "Oversensing." Exhibit 29

- MAUDE Report 2124215-2009-06833, submitted to the FDA on February 25, 2009, reported a Teligen device with a malfunction event. The report showed "Loose or intermittent connection." Exhibit 30

- MAUDE Report 2124215-2009-05399, submitted to the FDA on February 25, 2009, reported a Teligen device with an injury event. The report showed "High impedance; Oversensing; Failure to pace or properly pace; Noise." Exhibit 31

XIII. COUNTS

COUNT I

FEDERAL FALSE CLAIMS ACT, 31 U.S.C. §§ 3729(a)(1)(A)-(B) AGAINST BOSTON SCIENTIFIC FOR DEFECTIVE DEVICES

273. Relator realleges and incorporates by reference the preceding paragraphs as if fully set forth herein.

274. Beginning in August 2008 and continuing through July 2009, Defendant Boston Scientific has knowingly manufactured and sold defective Cognis and Teligen cardiac devices to hospitals and other providers, knowing that hospitals and other providers would bill the government for the defective devices and for implantation (as approximately two-thirds of defibrillator implants are paid for by government payors). As a result, Boston Scientific knowingly caused hospitals and other providers to submit false claims to Medicare, Medicaid and other federal health care programs in violation of FDA regulations for defective, misbranded and/or medically unnecessary devices. Through this conduct, Defendant Boston Scientific knowingly caused hospitals and other providers to present false or fraudulent claims for payment to the United States in violation of Section 3729(a)(1)(A) of the Act. Such claims caused actual damages to the United States.

275. Further, throughout the relevant time period, Defendant Boston Scientific has knowingly caused hospitals and other providers to make or use a false records or statements material to false or fraudulent claims – including express and/or implied certifications that the defective, misbranded and/or medically unnecessary cardiac devices, Cognis and Teligen, were in fact medically necessary and in compliance with FDA regulations – in order to obtain reimbursement from Medicare, Medicaid and other federal health care programs. Through these

acts, Defendant has knowingly caused to be made or used false records or statements material to false or fraudulent claims to the United States, in violation of Section 3729(a)(1)(B) of the Act. Such claims caused actual damages to the United States.

COUNT II

**CALIFORNIA FALSE CLAIMS ACT,
CAL. GOV'T CODE §§ 12651(a)(1) and (a)(2)
AGAINST BOSTON SCIENTIFIC
FOR DEFECTIVE DEVICES**

276. Relator realleges and incorporates by reference the preceding paragraphs as if fully set forth herein.

277. Beginning in August 2008 and continuing through July 2009, Defendant Boston Scientific has knowingly manufactured and sold defective Cognis and Teligen cardiac devices to hospitals and other providers, knowing that hospitals and other providers would bill the government for the defective devices and for implantation (as approximately two-thirds of defibrillator implants are paid for by government payors). As a result, Boston Scientific knowingly caused hospitals and other providers to submit false claims in violation of FDA regulations to Medi-Cal for defective, misbranded and/or medically unnecessary devices. Through this conduct, Defendant Boston Scientific knowingly caused hospitals and other providers to present false or fraudulent claims for payment to Medi-Cal in violation of Section 12651(a)(1) of the Act. Such claims caused actual damages to the State.

278. Further, throughout the relevant time period, Defendant Boston Scientific has knowingly caused hospitals and other providers to make or use a false records or statements material to false or fraudulent claims – including express and/or implied certifications that the defective, misbranded and/or medically unnecessary cardiac devices, Cognis and Teligen, were in fact medically necessary and in compliance with FDA regulations – in order to obtain

reimbursement from Medi-Cal. Through these acts, Defendant has knowingly caused to be made or used false records or statements material to false or fraudulent claims to California, in violation of Section 12651(a)(2) of the Act. Such claims caused actual damages to the United States.

REQUESTS FOR RELIEF

WHEREFORE, Relator, on behalf of the United States and the State of California, demands that judgment be entered in his favor and against Defendant for the maximum amount of damages and such other relief as the Court may deem appropriate on each Count. This includes, with respect to the Federal False Claims Act, three times the amount of damages to the Federal Government plus civil penalties of no more than Eleven Thousand Dollars ($11,000.00) and no less than Five Thousand Five Hundred Dollars ($5,500.00) for each false claim, and any other recoveries or relief provided for under the Federal False Claims Act.

This Request also includes, with respect to the California False Claims Act, the maximum damages, fine and penalties permitted by the Act, and any other recoveries or relief provided for under the Act.

Further, Relator requests that he receive the maximum amount permitted by law of the proceeds of this action or settlement of this action collected by the United States and the State of California, plus reasonable expenses necessarily incurred, and reasonable attorneys' fees and costs. Relator requests that his award be based upon the total value recovered, both tangible and intangible, including any amounts received from individuals or entities not parties to this action.

Finally, pursuant to Federal Rule of Civil Procedure 38(b), Relator demands a jury trial on all issues so triable.

Dated: September 19, 2017

Respectfully submitted,

/s/ Joy Clairmont

Daniel R. Miller
(PA Bar No. 68141; DE Bar No. 3169)
Joy Clairmont (PA Bar No. 82775)
BERGER & MONTAGUE, P.C.
1622 Locust Street
Philadelphia, PA 19103
(215) 875-3000
dmiller@bm.net
jclairmont@bm.net

- and -

E. Michelle Drake
MN Bar No. 0387366
BERGER & MONTAGUE, P.C.
43 SE Main Street, Suite 505
Minneapolis, MN 55414
(612) 494-5999
emdrake@bm.net

Attorneys for Plaintiff Relator